even if they are not provider-based, would be made under the Medicare acute care hospital inpatient prospective payment system.

In deciding whether to make a provider-based determination with respect to a particular facility, it would not be significant that the facility might have a low rate of Medicare utilization, might be utilized by only Medicare or only Medicaid patients, or might not have admitted any Medicare or Medicaid patients in a particular period. The fact that the facility furnishes types of services that are billable under Medicare or Medicaid, or both, would be sufficient to make a determination appropriate.

We proposed to retain the rules that a department of a provider or a remote location of a hospital (such as, for example, one campus of a multicampus hospital) may not by itself be qualified to participate in Medicare as a provider under the regulations on provider agreements in § 489.2, and the Medicare conditions of participation do not apply to a department as an independent entity. However, we proposed to delete the requirement at § 413.65(a)(2) that such a department may not be licensed to provide services in its own right. Some States require separate licensing of facilities that Medicare would treat as a department of a hospital or other provider. In these States, we would not require a common license. We proposed to retain the provision that, for purposes of Part 413, the term ''department of a provider'' does not include an RHC or, except as specified in § 413.65(m), an FQHC. (As explained below, existing § 413.65(m) is being redesignated as § 413.65(n) in this final rule.)

Questions have arisen regarding whether the provider-based criteria in § 413.65 are applicable in determining payment for ambulance services. Medicare is converting payment for ambulance services to a fee schedule, as described in a final rule published on February 27, 2002 (67 FR 9100). The ambulance fee schedule is effective April 1, 2001, and involves a transition period. During this transition period, the status of an ambulance supplier as provider-based could influence the amount of Medicare payment. However, the specific provider-based criteria in § 413.65 were not developed for ambulance suppliers, and we believe that many of these criteria could not reasonably be applied to them. Therefore, we did not propose to apply the criteria at § 413.65 to ambulance services.

We note that, in the May 9, 2002 proposed rule, we inadvertently did not make a conforming change to the regulations at § 413.65(a) to state that the provider-based rules do not apply to ambulances. Therefore, we are making this conforming change in this final rule.

Comment: One commenter recommended that all inpatient departments be exempt from the provider-based rules, regardless of whether they are on campus or off campus, since, due to their ''very status as inpatient departments, they are necessarily integrated into the operations of the main provider. * * *'' Several other commenters recommended that ancillary or other departments located within a hospital (that is, on campus) be deemed to be provider-based and thus not be required to show actual compliance with provider-based criteria.

Response: We do not agree that facilities that treat a patient population made up primarily or entirely of inpatients should necessarily be considered, on that basis alone, to be a fully subordinate and integral component of the main provider. There are instances where a Medicare payment differential exists between a hospital-based inpatient service and a freestanding service. For example, if an institution that primarily provides inpatient care is able to participate in Medicare as a part of a hospital, Medicare payment to the hospital will be made for the full range of inpatient hospital services defined in section 1861(b) of the Act. If the facility is not considered a part of a Medicare-participating hospital, Medicare payment would be made only for a much narrower range of services, such as physical and other therapies, which can be paid in ambulatory care settings. Compliance with the provider-based criteria is also needed to ensure that Medicare payment is made appropriately in merger situations, where the crucial issue is whether a facility is integral and subordinate to another that participates as a hospital. For example, under the TEFRA payment system applicable to psychiatric, children's and cancer hospitals, Medicare payment to the hospital for inpatient services usually is directly affected by the hospital-specific TEFRA target rate. If a particular hospital chooses to reorganize to include a new site that otherwise could participate in Medicare only as a separate hospital or as a remote location or satellite of still another hospital, the amount of payment would be affected. Similarly, for the reasons explained in detail in the May 9, 2002 proposed rule (67 FR 31482), a merger of two hospitals can significantly affect the payments made to them for their GME programs, even when each hospital is paid under the acute inpatient hospital prospective payment system. Under these circumstances, compliance with the provider-based criteria is also needed to warrant the higher payment level that would result.

We also do not agree that location on the main campus of a hospital should be the sole determinant of provider-based status, since hospitals can and frequently do lease space on their campuses to physicians and other providers or suppliers of health services, and these providers or suppliers may have no more connection to or integration into the hospital's operations than the lease agreement and physical proximity. For example, a hospital may lease some of its space to an independent diagnostic testing facility (IDTF) that furnishes radiology services, which are frequently considered by hospitals to be among their ancillary services. Such a facility could be paid significantly more as a provider-based department than as a freestanding facility. Because of this payment difference, we believe it is important that the facility meet standards that establish that it is an integral and subordinate part of the main provider hospital, and thus that the higher payment level associated with provider-based status is warranted. Therefore, we are not revising this final rule to permit on-campus facilities to qualify as provider-based solely because of location.

Comment: One commenter suggested that consolidations of facilities on separate campuses should not be subject to the provider-based requirements, but should be regulated only by the requirements on State licensure, Medicare certification, and Medicare enrollment.

Response: For the reasons explained in the response to the preceding comment, consolidation of facilities under a single provider number frequently has significant implications for Medicare payment levels. In many cases, the amount paid for services of a consolidated facility can be significantly more than the sum of what would be paid to two or more separate facilities for the provision of identical services. Current State licensure and Medicare certification requirements are focused on the protection of patient health and safety, and the determination of whether a facility is part of the main provider is not central to that concern. On the contrary, licensure and certification requirements may be easily manipulated by providers seeking to maximize payment under Medicare or Medicaid

without improving either the quantity or the quality of care furnished. Thus, it is crucial that we establish criteria to ensure that consolidated facilities are truly integral and subordinate to a single main provider.

Comment: Some commenters wrote on behalf of multicampus hospitals that operate under a single provider number and agreement, but include several campuses that are separately licensed by the State. The commenters stated that they have been structured in this way since before the inception of the Medicare program and thus did not adopt their current structures in an effort to maximize GME or DSH payments. The commenters explained that if multicampus hospitals are not exempted from the provider-based requirements, the hospitals would have to either designate one campus as the main campus and rearrange the clinical, financial, and other arrangements between the hospitals in order to comply with the provider-based requirements, or obtain a separate Medicare provider agreement and number for each campus. If the second course were chosen, total Medicare payment to the separate hospitals would be considerably less than what is currently being paid to them as multicampus organizations. Because the hospitals are unwilling to pursue either of the options outlined above, the commenter requested that either all multicampus hospitals be exempted from the provider-based requirements, or that an exemption be created for any such hospitals that have been structured as multicampus hospitals since the beginning of the Medicare program.

Response: We understand the commenter's concern, but for the reasons cited earlier in this preamble believe that it is important to apply the provider-based criteria to multicampus hospitals in which each campus is separately licensed, as well as to those in which all components operate under a single State license. In particular, such an exemption could lead to increased levels of Medicare GME and DSH payments, relative to the amounts payable if the provider-based criteria were applied. In fact, the commenter admitted that Medicare payment to the separate hospitals would be considerably less than what is paid to them as a single but multicampus hospital. We continue to believe it is important to pay for services of hospital facilities as part of a single hospital only when they meet the provider-based criteria we have established. Therefore, we are not adopting this comment.

Comment: One commenter requested more clarification of how the provider-based criteria apply to multicampus hospitals, and to multihospital systems (that is, chain organizations that include two or more hospitals, each of which participates separately in Medicare). The commenter was particularly interested in learning what would be the main campus of a multihospital system, and whether a facility or organization at one location of a multihospital system could be provider-based with respect to another hospital in that system.

Response: If a hospital comprises several sites at which both inpatient and outpatient care are furnished, it will normally be necessary for the hospital to designate one site as its ''main'' campus for purposes of the provider-based rules. Each of the other sites (referred to in our regulations as ''remote locations'') would then be expected to meet the provider-based requirements with respect to that main campus. Thus, any facility not located on a hospital's main campus would be considered to be an ''off-campus'' facility. Hospitals would normally be given considerable discretion in selecting which site is to be the ''main'' campus for provider-based purposes. In such a case, any outpatient facility also providing services at a ''remote location'' that are to be billed as services of the hospital would be considered as a potential hospital department for purposes of provider-based status and would be expected to meet the provider-based criteria with respect to the location designated by the hospital as its main campus. However, it is important to note that the provider-based criteria apply to individual hospitals, not to multihospital systems (for example, systems owned and operated by chain organizations). Where such a system exists, its hospitals will participate separately in Medicare, and the provider-based criteria will apply separately to each hospital in the chain. If a facility or organization located on the campus of one hospital in the chain wishes to be treated as part of another, separately participating hospital in the chain, the facility or organization would have to meet the provider-based criteria with respect to that hospital, on the same basis as if the two hospitals were not part of the same chain organization.

Comment: Several commenters stated that, in some areas, it is common for children's hospitals to set up and staff neonatal intensive care units (NICUs) in community hospitals, in order to extend these services into rural areas where they might not otherwise be available. The commenter noted that these units frequently cannot meet the location requirement for provider-based status in § 413.65(e)(3) of the proposed regulations, and asked that the final rule be revised to create a special exception to this requirement, to allow these units to continue to be treated as provider-based once the grandfathering period ends and to permit the creation of new units of the same type.

Response: We understand these commenters' concerns, but note that these units raise serious questions about the appropriate treatment of facilities located at long distances from the main children's hospital that nevertheless claim to be a part of that hospital. While these facilities may have very limited Medicare utilization, they frequently receive substantial amounts of payment under Medicaid, thus making it important to ensure that they are classified and paid appropriately. After considering these issues, we have concluded that it would not be appropriate to waive the location requirement for provider-based status, or make some other ad hoc exception to the provider-based criteria, for these facilities. However, we have explained in the FAQs the inability of units in certain locations to qualify for provider-based status does not preclude States from adopting revisions to their Medicaid plans to provide more generous payment to such units. While we are not making a special exception for NICUs, we recognize the importance of further emphasizing that when a payment difference exists, compliance with the provider-based rules is needed to justify payment for services in a facility as provider-based. Therefore, in this final rule, we are clarifying the regulations at § 413.65(a) to state that the determinations of provider-based status are made for payment purposes.

Comment: Some commenters requested clarification of how the provider-based criteria apply to multicampus hospitals that participate in Medicare under a single provider number but comprise two or more campuses that are physically separate from one another. The commenters were particularly concerned about which campus is to be identified as the main campus and about whether clinics or other facilities located on one campus of a hospital may be considered provider-based with respect to another campus.

Response: We agree that multicampus hospitals present special implementation issues. However, the following general principles will be applied. First, when hospital facilities are dispersed among two or more geographically separate campuses, it will be necessary for one of the campuses to be designated by the hospital as the main campus. Facilities at the other campus(es) would be

considered provider-based only if they meet the provider-based criteria in relation to the main campus. We would normally accept the provider's own selection of a main campus, unless the regional office concludes, in a particular case situation, that the campus selected by the provider clearly does not actually function as the main campus. The location requirements for a facility at a campus other than the main campus would be applied based on the distance between the facility and the main campus. Hospital chain organizations, which include a number of separately certified hospitals, would not be considered multicampus hospitals.

Comment: One commenter stated that the provider-based criteria are being applied under Medicaid only because the same certification standards apply under Medicaid as under Medicare. The commenter also pointed out that States are not required to follow Medicare payment system rules in making payment under their Medicaid programs. The commenter then argued that this State flexibility to determine Medicaid payment means that CMS should prohibit States from applying the provider-based criteria in determining payment under Medicaid.

Response: The commenter is correct in noting that the Medicaid regulations at 42 CFR 440.10 and 440.12 define inpatient and outpatient hospital services, for Medicaid purposes, as services furnished in or by an institution that meets the requirements for participation in Medicare as a hospital. Medicare participation by an institution as a hospital is contingent on the institution's compliance with many participation requirements, not merely the health and safety rules set forth in 42 CFR Part 482. The institution is also required under section 1866 of the Act and regulations at 42 CFR Part 489 to comply with various other statutory and regulatory provisions relating to (among other areas) charges to beneficiaries, maintenance of billing and other records, and the screening and stabilization, or appropriate transfer, of emergency cases. To the extent the hospital is required to comply with the provider-based criteria in Medicare regulations as part of its Medicare hospital participation obligations, the definitions of services in § 440.10 and 440.12 also require that it comply with these requirements for Medicaid purposes.

Regarding the commenter's remarks on State flexibility, we recognize that States are authorized to adopt, through their State plans, payment definitions and methods that differ from those used under Medicare. Thus, the commenter is correct in noting that a State may adopt payment methods that do not differentiate between facilities that meet the provider-based requirement and those that do not. To the extent that States amend their State plans to contain such payment methods, we do not object to these actions. However, we do not believe it would be consistent with State flexibility to prohibit States that wish to apply provider-based criteria in making their payment decisions from doing so. Such a prohibition would not benefit either States or their Medicaid recipients and, on the contrary, could increase State and Federal Medicaid spending unnecessarily. Therefore, we are not making any change in this final rule based on this comment.

Comment: Several commenters noted that Indian Health Service (IHS) and tribal clinics and other facilities meeting the criteria in § 413.65(l) (redesignated as § 413.65(m) in this final rule) are in effect excluded from the scope of the provider-based criteria by the grandfathering provision included in that section. The commenters further noted that under Public Law 93–638, the Indian Self-Determination Act, as amended, tribes have the right to contract for the management of all or a portion of the IHS programs that provide services in their communities. The commenters pointed out that tribal and IHS facilities remain the primary source of health care in many remote rural communities. However, because of the unique IHS and tribal administrative systems, many clinics and other facilities that might lose their grandfathered status under § 413.65(l) (redesignated as § 413.65(m) in this final rule) are not able to meet provider-based criteria. To avoid disrupting the operation of these vital sources of care in remote rural areas, and consistent with the objectives of the Indian Self-Determination Act, the commenters recommended that all clinics and other facilities operated by IHS or tribes should be exempted from the provider-based regulations.

Response: We understand the concern about the need to preserve access to health care by patients using IHS facilities in rural communities. However, we note that existing § 413.65(l) provides grandfathering protection for the facilities in operation when the existing provider-based rules were published, and that section 432 of BIPA amended the Medicare statute to permit payment for physician services in IHS clinics, thus providing an alternate funding source for facilities that become freestanding. Therefore, we do not believe a further change of the kind recommended by the commenter is needed.

Comment: One commenter noted that excluding facilities providing only physical, occupational, or speech therapy to ambulatory patients from the provider-based requirements does not meet CMS' own stated criteria for such exclusions, in cases where those facilities are operated by CAHs. A payment difference based on provider-based or freestanding status would exist in such cases. If such facilities were operated as freestanding they would be paid on a fee schedule basis. However, if they were operated as integral and subordinate parts of CAHs, they would be paid on the same reasonable cost basis as other components of the CAH. The commenter recommended that the exclusion language in § 413.65(a)(1)(ii)(H) be revised to state that the exclusion applies to such facilities other than those which are operated as part of a CAH.

Response: We agree and are revising this final rule to reflect this comment.

Accordingly, we are adopting as final the proposed revision to § 413.65(a)(1)(ii)(G), the addition of § 413.65(a)(1)(ii)(J), and the revisions of the definitions of ''Department of a provider,'' ''Provider-based entity'' and ''Remote location of a hospital under § 413.65(a)(2). In addition, in response to public comments, we are revising existing § 413.65(a)(1)(ii)(H) to clarify that the exclusion of facilities providing only physical, occupational, or speech therapy to ambulatory patients applies to these facilities only if they are not operated as part of a CAH.

b. Further Delay in Effective Date of Provider-Based Rules

As noted earlier, § 413.65(b) was recently revised to reflect the ''grandfathering'' provision in section 404(a)(1) of BIPA. Under that provision, if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until October 1, 2002.

To allow hospitals and other facilities the time they need to make contractual and organizational changes to comply with the new rules, and to ensure that CMS Regional Offices and contractors are able to provide for an orderly transition to the new provider-based rules, we believed an additional delay in the effective date of the provider-based criteria is needed. Therefore, in the May 9, 2002 proposed rule we proposed to revise § 413.65(b)(2) to state that if a facility was treated as provider-based in relation to a hospital or CAH

on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. We proposed to further provide that the requirements, limitations, and exclusions specified in § 413.65(d) through (j) (as proposed to be redesignated) will not apply to that hospital or CAH for that facility until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of paragraph (b)(2), a facility would be considered as having been provider-based on October 1, 2000, if on that date it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital. We proposed to make the new requirements effective on October 1, 2002, with respect to provider-based status for facilities not qualifying for the grandfathering provision.

Comment: One commenter requested clarification of how the proposed delay in effective date for the facilities grandfathered under section 404(a) of BIPA will be applied. Specifically, the commenter asked whether facilities benefiting from the grandfathering would be able to take advantage of any additional flexibility provided under the final rules before the hospital's first cost reporting period beginning on or after July 1, 2003.

Response: As explained in the preamble to the proposed rule, the purpose of the delayed effective date for grandfathered facilities is to allow more time for any necessary contractual or organizational changes that hospitals or their grandfathered facilities might need to undertake to achieve actual compliance with the provider-based criteria. Under our proposal, this would be accomplished by simply extending the BIPA mandated grandfathering provision until the hospital's first cost reporting period beginning on or after July 1, 2003. To clarify the effect of the delay, we are revising the final rule to specify that the grandfathering provision applies to the requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of § 413.65 of this final rule. To the extent a particular grandfathered hospital might benefit from any other changes in paragraphs of § 413.65 other than those listed in the immediately preceding sentence, it would be able to receive that benefit as of October 1, 2002, which is the effective date of any revisions to the other paragraphs.

Comment: Several commenters requested that the grandfathering of facilities treated as provider-based on October 1, 2000 should continue indefinitely, not just until the start of the first cost reporting period on or after July 1, 2003, as we had proposed.

Response: We are providing an extension in the effective date of the provider-based rules for grandfathered facilities until cost reporting periods beginning on or after July 1, 2003, to allow these facilities sufficient time to make any contractual and organizational changes needed to comply with the new rules. However, we do not believe it is appropriate to allow the facilities that were treated as provider-based in the past to continue to be treated that way permanently, without ever having to meet the same requirements as newer facilities. To do so would create a permanent double standard under which some older facilities would continue indefinitely to be rewarded for their previous inappropriate billing. We note that even the statutory provision under section 404(a) of BIPA was set for a limited 2-year time period.

Comment: One commenter suggested that grandfathering be provided for all hospital facilities for which affirmative determinations of provider-based status had been made by CMS (previously, HCFA) before October 1, 2000, or that such facilities be presumed to meet the provider-based criteria in the revised regulations without having to attest to compliance with those criteria, so that any future determination that a facility is not provider-based would be applied on a prospective basis only.

Response: For the reasons noted above, we do not believe a general grandfathering of facilities is appropriate. In addition, the criteria in the program memorandum and instructions in effect before October 1, 2000, differ from the new proposed rules to be effective on October 1, 2002. Therefore, we do not believe it is appropriate to assume that facilities that received a provider-based determination under a prior set of criteria meet the new set of provider-based criteria in this final rule. Regarding the recommendation that any revised determination be made effective on a prospective-only basis, we note that, under § 413.65(c)(2), providers that have received affirmative determinations of provider-based status with respect to facilities or organizations are required to report material changes in the relationships between themselves and any provider-based facility or organization. A provider having a determination of provider-based status will need to comply with this rule and, in particular, as stated in revised § 413.65(l)(1), will need to report any aspect of its ownership or operation of the facility that it reasonably believes might not meet applicable provider-based requirements, to ensure that any redeterminations are made effective only prospectively.

Accordingly, we are adopting as final the proposed revision to § 413.65(b)(2), with a further clarification in response to a comment that the grandfathering provision applies to the requirements, limitations, and exclusions of § 413.65 (d), (e), (f), (h), and (i) only.

c. Revision of Application Requirement

Existing regulations at § 413.65(b)(2) establish an explicit application requirement for all facilities seeking provider-based status, except for grandfathered facilities and those treated as provider-based pending a determination on an application filed on or after October 1, 2000, and before October 1, 2002. Under existing § 413.65(b)(3), a main provider or a facility must contact CMS, and the facility must be determined by CMS to be provider-based, before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report. Many providers and provider representatives have expressed concern that the requirement to file an application will increase paperwork burden for hospitals unnecessarily. In response to these concerns, in the May 9, 2002 proposed rule, we proposed to revise the application requirements as follows:

First, we proposed to delete the existing application requirement under § 413.65(b)(3). We proposed to revise this section to state that except where payment is required to be made under BIPA, as specified in proposed revised § 413.65(b)(2) and (b)(5), if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that its facility meets the criteria in § 413.65(d) and, if it is a hospital, also attest that its facility will fulfill the obligations of hospital outpatient departments and hospital-based entities, as described in proposed § 413.65(g). We also proposed to require the provider to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request. We noted that, under this proposal, there would no longer be an explicit requirement that a provider-based approval be obtained before a facility is treated as provider-based for billing or cost reporting purposes. It

could benefit the provider to obtain a determination because, under the proposed § 413.65(l)(1) treatment of a facility as provider-based would cease only with the date that CMS determines that the facility no longer qualifies for provider-based status, if the reason the provider-based criteria are not met is a material change in the provider-facility relationship that was properly reported to CMS. By contrast, a provider which did not seek such a determination or obtained a determination but failed to report a material change in its relationship with the facility, could face a partial recovery of past payments. Also, under proposed § 413.65(j) (Inappropriate treatment of a facility or organization as provider-based) a provider that does not seek a provider-based determination and incorrectly bills as such could be subject to the partial recovery of payments for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. We further proposed that if the facility is not located on the main campus of the potential main provider, the provider that wishes to obtain an advance determination of provider-based status would be required to submit an attestation stating that its facility meets the criteria in proposed revised §§ 413.65(d) and (e) and, if the facility is operated as a joint venture or under a management contract, the requirements in proposed §§ 413.65(f) and (h), as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in proposed revised § 413.65(g). The provider seeking such an advance determination would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations. We believe the use of an attestation process would strike an appropriate balance between the legitimate interests of hospitals in reducing paperwork and reporting, and the equally legitimate need of CMS to ensure proper accountability for compliance with the qualification requirements for a status that typically leads to a higher level of Medicare or Medicaid payment.

We noted that, under the proposed revisions to the application procedures at § 413.65(b), a hospital would not be explicitly required to submit an application and receive a provider-based determination for a facility before the time at which the hospital may bill for services at that facility as provider-based. However, we indicated that, alternatively, we would consider retaining the existing regulations at § 413.65(b)(2) which state that, except where payment is required to be made under BIPA as specified in proposed revised §§ 413.65(b)(2) and (b)(5), hospitals are explicitly required to submit provider-based applications, and to withhold billing as provider-based until CMS determines that a facility meets the provider-based rules. In the May 9, 2002 proposed rule, we specifically solicited comments on the appropriateness of this or other alternative application procedures.

Comment: Some commenters stated that although it appears that the mandatory application requirement under the existing regulations has been replaced with the voluntary attestation process, the preamble of the May 9, 2002 proposed rule made several references to procedures for applying for provider-based status. The commenters stated that if such references to an application in the final rule must be maintained in order to deal with applications submitted prior to the creation of the attestation process, such references should be clarified accordingly.

Response: While we have proposed to replace the mandatory requirement for provider-based determinations under existing § 413.65(b) with a voluntary attestation process, we note that providers still have the option of obtaining a determination of provider-based status for their facilities, which we encourage. The proposed method for doing so is through the attestation process. Under § 413.65(b)(3), the provider may obtain a determination of provider-based status by submitting an attestation stating that the facility meets the relevant provider-based requirements (depending on whether the facility is located on campus or off campus).

As we stated in the May 9, 2002 proposed rule (67 FR 31481), ''Until a uniform application is available, at a minimum, the request should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the application is submitted.'' For purposes of this final rule, we are clarifying that, effective October 1, 2002, an attestation of provider-based status has the same effect as a request for provider-based status, in that approval of an attestation would result in a determination that a facility or organization is provider-based. Prior to October 1, 2002, the effective date of the final rule (or, in the case of grandfathered facilities, prior to the start of the provider's first cost reporting period beginning on or after July 1, 2003), the provider would submit a request for provider-based determination (as opposed to an attestation). (Until the effective date of these regulations on October 1, 2002, providers should contact their CMS Regional Offices for information regarding application procedures). For providers wishing to obtain a provider-based determination after October 1, 2002, the providers would submit an attestation to CMS. Accordingly, until a uniform request or attestation form is available, at a minimum, the provider should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the request or attestation is submitted. The provider must also enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus) and the date on which the facility became provider-based to the main provider. Documentation in support of the attestation of provider-based status must be submitted with the attestation for facilities located off campus. Main providers that submitted a request for a provider-based determination after October 1, 2000, but prior to the publication of this final rule, would be protected under section 404(c) of BIPA from recovery of overpayments in periods prior to the date on which CMS determines a facility is not provider-based.

We note that even though we proposed to remove the current general requirement that a determination of provider-based status be obtained, we did not propose to revise paragraph (n) of § 413.65 (redesignated in this final rule as paragraph (o)). That paragraph states that provider-based status cannot be effective before the earliest date on which a request for provider-based status has been made and all requirements of 42 CFR Part 413 have been met. To avoid creating confusion for providers and contractors and to allow the regulations to be implemented properly, we are making a conforming change to paragraph (o) to eliminate any reference to a mandatory application or determination, with one exception. As explained later in this preamble, we also state in § 413.65(o) that if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) for certain time periods, or previously was

determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS, CMS will not treat the facility or organization as provider-based for payment until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under Part 413.

Comment: One commenter stated that the proposed rules do not appear to provide hospitals that submit an attestation with any benefit with respect to recoupment of overpayments. For example, the commenter stated that, under the proposed rule, a provider could submit an attestation and begin providing and billing for provider-based services for years before receiving a determination from CMS that it is not provider-based and consequently be subject to the recovery of payments if CMS later determines that the facility is not provider-based. The commenter requested that a provider that submits a complete attestation not be liable for recovery of overpayments, but rather it should only be improper to bill as provider-based subsequent to a determination by CMS that a facility is not provider-based. Another commenter expressed concerns about possible long delays by CMS in reaching decisions on attestations and recommended that CMS require its regional offices to approve or disapprove provider-based status for each facility within 60 days after having received the attestation regarding that facility. Another commenter stated that it would like a written response to the attestations and accompanying documentation from CMS for the providers to keep on file.

Response: We do not agree that it would be appropriate to allow a provider that has attested inaccurately to being provider-based to retain payments made to the provider as if the facility were in full compliance with provider-based criteria. However, CMS would not recover all past payments for periods subject to reopening, but instead would recover only the difference between the amount of payment that actually was made since the date the complete request for a provider-based determination was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. At the time that CMS determines that a facility that submitted a complete attestation is actually not provider-based, payment would continue for up to 6 months but only at a reduced rate as described at § 413.65(j)(5).

Regarding the timeliness of action on attestations, we agree that providers should not be subject to long delays before action is taken. In response to this and other comments requesting further information on the procedures CMS will follow when an attestation is received, we are revising § 413.65(b)(3) by adding new paragraphs (iii) and (iv). In new paragraph (b)(3)(iii), we are clarifying that whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the criteria in § 413.65, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility is provider-based. In new paragraph (b)(3)(iv), we are clarifying that whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the criteria in § 413.65, consistency with the documentation submitted with the attestation, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility is provider-based.

We also will work with our regional offices and intermediaries as necessary to ensure that providers that submit attestations receive a prompt response. However, because of workload considerations and uncertainty about the volume of attestations that may be received, we have not yet specified a timeframe for completion of action on an attestation.

Comment: One commenter recommended that if CMS finds an attestation to be incomplete, the provider be given an additional 30 days to submit supplementary information in support of the attestation.

Response: We agree that providers who inadvertently omit needed information from an attestation should be given a reasonable opportunity to supplement that information. However, at the same time, we agree with the commenters who pointed out the importance to the provider of receiving a timely decision on whether a particular facility qualifies for provider-based status. If CMS were to delay a decision for a provider that repeatedly submitted incomplete attestations, this would prevent a timely response and could defeat the purpose of the attestation procedure. We intend to develop further implementing instructions and procedures that will strike a reasonable balance between the need for additional information and the need for a timely decision.

Comment: One commenter requested that we reiterate that, since providers are no longer required under the proposed revised regulations to submit an attestation or an application for provider-based status as a precondition to billing for provider-based services, CMS would only consider a provider to be billing inappropriately if the provider was wrong in its conclusion that it meets the provider-based requirements. The commenter also asked that we clarify that facilities grandfathered under BIPA also need not submit an attestation, even at the expiration of the grandfathering period. Facilities grandfathered by BIPA will be treated the same as all other facilities on the date that their grandfathering period expires, which is the start of the cost reporting periods that begin on or after July 1, 2003.

Response: The commenter is correct in the view that providers, regardless of whether they are grandfathered under BIPA, are not obligated to submit attestations or applications for provider-based status before they begin billing as provider-based, and that a provider would only be considered to be billing inappropriately if the facility actually did not meet the relevant provider-based rules. However, we note that if a provider does not submit a complete attestation of provider-based status, and CMS subsequently determines that the provider is billing inappropriately, the provider would be subject to recovery of overpayments under § 413.65(j)(ii) for services at that facility(ies) for all prior cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889.

Comment: One commenter noted that all hospitals, even those previously subject to grandfathering, will be subject to the new regulations as of their first cost reporting periods starting on or after July 1, 2003. In view of this obligation, the commenter believed that it is unnecessary for attestations to be submitted for any facilities that are located on the campus of the hospital that claims them as provider-based. The commenter also recommended that if CMS later determines that the facility does not meet the provider-based criteria, CMS should not recover any past payments attributable to improper billing, but apply its determination only prospectively.

Response: As explained more fully earlier in this preamble, under these final rules, while the provider-based criteria must be met, no provider is required to submit an attestation for any facility as a precondition to billing for its services as a provider-based facility. This is the case even where the facility is located on the main campus of a hospital. However, we believe an attestation has value, in that a provider that makes such an attestation presumably does so after having reviewed the provider-based criteria and assessed a particular facility's structure and operations in relation to them. Moreover, the attestation relates to compliance with only a minimal level of integration, and does not require any supporting documentation. Therefore, we do not believe that providing an attestation will require an unreasonable level of effort from the provider.

Comment: One commenter recommended that off-campus facilities be required to submit attestations of compliance with the provider-based criteria before the date on which the revised regulations become effective for them. (For grandfathered facilities, §§ 413.65(d), (e), (f), (h), and (i) of the revised regulations would become effective for the hospital's first cost reporting period starting on or after July 1, 2003.) The commenter also recommended that if these facilities are later found not to have met the provider-based requirements, any determination that they are not provider-based should be applied only prospectively.

Response: As explained in response to a previous comment, we cannot agree that a provider should be allowed to retain payments made as if a facility were provider-based after a determination has been made that the provider-based criteria were not met. Therefore, this final rule provides for recovery of past payments to the extent necessary to make those payments relate more closely to what would have been paid if the facility's services had been billed on a freestanding basis.

Comment: One commenter expressed approval of our proposal under which supporting documentation would not have to be submitted with the attestation for on-campus facilities. The commenter suggested that the paperwork burden for providers could be further reduced if the regulations were revised to eliminate the need for supporting documentation for attestations regarding off-campus facilities or organizations as well. Another commenter stated that hospital-licensed community health centers frequently are located within a few miles of the main provider-campus and are closely integrated with it. The commenter believed these facilities should not be required to submit supporting documentation.

Response: We understand and share the commenters' interest in reducing the paperwork burden on providers. However, this important objective must be balanced against the equally important need to ensure proper accountability by providers for the status of the facilities or organizations for which they are claiming provider-based status. Determining whether an off-campus facility is truly integrated with a main provider is more difficult than for a facility located on the main campus of a provider, and this is why there are additional requirements for off-campus facilities to demonstrate provider-based status. In view of this, we believe it is reasonable to require that an attestation regarding an off-campus facility, including hospital-licensed community health centers, be accompanied by supporting documentation that clearly shows the basis for the attestation.

Comment: One commenter noted that proposed § 413.65(b)(3)(i) requires a provider that makes a provider-based attestation with regard to an on-campus facility to make documentation supporting that attestation available to CMS upon request. The commenter recommended that the regulation be revised to require that the supporting documentation also be made available to CMS contractors (fiscal intermediaries and carriers) upon request. *Response:* We agree, and are revising the final rule accordingly.

Comment: One commenter asked CMS to provide guidance as to the type of documentation that is required to be submitted with an attestation for an off-campus facility. Another commenter suggested that before a uniform application is available, providers should be required to submit information regarding physical location, a contact person, and the date the facility became provider-based to the main provider.

Response: As stated above, until a uniform attestation form is available, at a minimum, the attestation should include the identity of the main provider and the facility(ies) or organization(s) for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the application is submitted. The provider must also enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus) and the date on which the facility became provider-based to the provider. We plan on issuing further guidance in program instructions after publication of this final rule.

Comment: One commenter noted CMS' authority to terminate payment prospectively if a provider fails to provide all necessary information as part of the continuation of payment provisions under § 413.65(j)(5). Given this authority, and because the commenter believed it will be difficult for providers to know what constitutes a complete attestation, the commenter recommended that CMS provide the opportunity for providers to supplement their original submissions with additional information within 30 days of receipt of notice from CMS that the submission is incomplete.

Response: Under § 413.65(b)(3), a complete request (or attestation) is one that includes all information needed to permit CMS to make a determination. We have stated above that we plan to issue further guidance as to what information should be included in an attestation. However, we note that, under § 413.65(j)(5), a provider must notify CMS in writing within 30 days of the date that CMS issues its denial of provider-based status, of whether the provider intends to seek a determination of provider-based status for the facility or whether the practitioners will be seeking to enroll to bill Medicare or Medicaid for services at that location as a freestanding facility. If the provider notifies CMS of its intentions within 30 days, the provider has up to 6 months to take whatever steps are necessary to comply with the relevant rules, whether that means providing CMS with supplemental documentation or making changes to meet the regulatory requirements (for example, a provider is renegotiating its management contracts). Therefore, we believe it is unnecessary to add an additional 30 days to the interim period in which payment continues at a reduced rate.

Comment: One commenter asserted that if CMS has concerns about the status of on-campus facilities, it should be incumbent on CMS to initiate an investigation and to provide notice to the provider and opportunity for the facilities to fix any discrepancies prior to losing provider-based status. The commenters added that it is still unclear whether every service on the hospital's campus would need to submit an attestation, or if one attestation is sufficient to cover all on-campus facilities. Some commenters also asked whether, and in what timeframe, these sites will receive a written response from CMS.

Response: We do not agree with this commenter's suggestion that providers that have been inappropriately treating certain facilities as provider-based and have not attempted to obtain a provider-based determination should be protected from recovery of past overpayments. However, we note that § 413.65(j)(5) of this final rule would allow such a provider up to 6 months of continued payment, at an adjusted rate, to meet applicable billing requirements.

In regard to the commenter's request for clarification concerning whether every service on the hospital's campus would need to submit an attestation, or if one attestation is sufficient to cover all on-campus facilities, we emphasize that the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole. That is, the facility in its entirety must be a subordinate and integrated part of the main provider. For example, a provider may have several outpatient facilities, some located on campus and some located off campus, yet each facility as a whole must meet the applicable rules for provider-based status. However, a main provider would not need to submit a separate application for each one of its facilities for which a provider-based determination is sought. A provider may attest in a single application package that each one of its facilities in which it intends to bill for services as if the facility is provider-based meets the applicable provider-based rules under § 413.65. For those facilities that are located on campus, no documentation is required to be submitted with the attestation. Documentation must be submitted for those facilities located off campus. However, we are requiring that as part of its attestation, the main provider enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus).

As noted earlier, the commenters also asked whether, and in what timeframe, a provider that submits an attestation will receive a written response from CMS. While we are making revisions in these final rules to provide more information about the actions CMS will take in response to such an attestation, at this time, due to the uncertainty of the volume of requests that will be submitted by providers, we cannot state an exact timeframe in which the provider-based determinations will be made for on-campus or off-campus facilities. Each attestation will be received and processed by the appropriate CMS Regional Office (or fiscal intermediary) and will be reviewed as soon as possible.

Comment: One commenter asked if a ''re-attestation'' is required after a certain period of time.

Response: Just as providers are no longer explicitly required to submit an initial attestation, there is also no explicit requirement for hospitals to re-attest that their facilities continue to meet the provider-based requirements. However, we note that, under proposed § 413.65(k) (revised as § 413.65(l) in this final rule), if CMS determines that a facility that had previously been determined to be provider-based no longer qualifies for provider-based status, and the failure to qualify for provider-based status results from a material change in the relationship between the main provider and the facility that the main provider *did* report to CMS, treatment of the facility as provider-based would cease with the date that CMS determines that facility no longer qualifies for provider-based status. Conversely, if a main provider *did not* report a material change to CMS, the main provider will be subject to recovery of overpayments as described under § 413.65(j)(1)(ii).

Comment: One commenter stated that the use of the term ''advance determination'' is confusing because the rule does not provide for an advance determination of provider-based status.

Response: We agree with the commenter and are removing all references to ''advance'' used in connection to provider-based determinations from this final rule. We note that, under proposed § 413.65(k) (revised as § 413.65(l) in this final rule), a provider that submits a complete attestation of compliance with the provider-based status requirements for a facility that has not previously been found by CMS to have been inappropriately treated as provider-based, may bill and be paid for services of the facility as provider-based from the date of its attestation of provider-based status until the date that CMS determines that the facility is not provider-based.

Accordingly, we are adopting as final the proposed changes to § 413.65(b)(3) with the following modifications: We are revising § 413.65 by adding new paragraphs (b)(3)(iii) and (iv) to include further information on procedures for submitting and processing attestations; removing references to the term ''advance'' in connection with determinations in paragraphs (b)(3)(i) and (ii); and adding language under paragraph (b)(3)(i) regarding the availability of documentation to contractors.

d. Requirements Applicable to All Facilities or Organizations

Under existing § 413.65, all facilities seeking provider-based status with respect to a hospital or other main provider must meet a common set of requirements. These include requirements relating to common licensure (paragraph (d)(1)), operation under the ownership and control of the main provider (paragraph (d)(2)), administration and supervision (paragraph (d)(3)), integration of clinical services (d)(4)), financial integration (paragraph (d)(5)), public awareness (paragraph (d)(6)), and location in the immediate vicinity of the main provider (paragraph (d)(7)). (In addition, as described more fully below, specific rules applicable to all facilities rule out provider-based status for facilities operated as joint ventures by two or more providers (paragraph (e)) and limit the types of management contracts that facilities seeking provider-based status may operate under (paragraph (f)).)

Since publication in final of the existing provider-based rules in April 2000, hospitals and other providers have expressed concern that the requirements outlined above are overly restrictive and do not allow them enough flexibility to enter into appropriate business arrangements with other facilities. We understand these concerns, and agree that Medicare rules should not restrict legitimate business arrangements that do not lead to abusive practices or disadvantage Medicare beneficiaries. At the same time, we believe our existing rules provide a high level of assurance that a facility complying with them is, in fact, an integral and subordinate part of the facility with which it is based, and do not accord provider-based status to facilities that are not integral and subordinate to a main provider, but in fact have only a nominal relationship with that provider.

After considering all comments received on these issues, we believe that further changes in the provider-based rules would be appropriate. In particular, we agree with those who argue that a facility's or organization's location relative to the main campus of the provider is relevant to the integration that is likely to exist between the facility or organization and the main provider. For example, if a facility or organization is located on the main campus of a provider, is operated under the main provider's State license, is medically and financially integrated with that provider, and is held out to the public and other payers as a part of that provider, we believe the necessary

degree of integration of the facility or organization into the main provider can be assumed to exist. We also are concerned that further prescribing the types of management contracts or other business arrangements that may exist between the main provider and the facility or organization would unnecessarily restrict its flexibility to establish cost-effective agreements without significantly enhancing the integration of the facility or organization into the main provider. Therefore, in the May 9, 2002 proposed rule, we proposed to simplify the requirements applicable to facilities or organizations located on the campus of the main provider (as campus is defined in existing regulations at § 413.65(a)(2)). Under our proposal, all facilities seeking provider-based status, including both on-campus and off-campus facilities, would be required to comply with the existing requirements regarding licensure, clinical services integration, financial integration, and public awareness. (These requirements are currently codified at §§ 413.65(d)(1), (d)(4), (d)(5), and (d)(6) and were proposed to be redesignated as paragraphs (d)(1) through (d)(4), respectively, of § 413.65.)

With respect to financial integration, existing regulations at § 413.65(d)(5) require that the financial operations of the facility or organization be fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The regulations also require that costs of a provider-based facility or organization be reported in a cost center of the provider, and that the financial status of any provider-based facility or organization be incorporated and readily identified in the main provider's trial balance.

Some hospital representatives have questioned the appropriateness of requiring that the costs of a remote location of a hospital be reported in a single cost center, noting that such costs ordinarily would appear in multiple cost centers of the main provider, with (for example) employee health and welfare costs of the remote location being included in the corresponding cost center of the main provider. In recognition of this concern, in the May 9, 2002 proposed rule, we proposed to revise the requirement to state that the costs of a facility or organization that is a hospital department must be reported in a cost center of the provider, and that costs of a provider-based facility or organization other than a hospital department must be reported in the appropriate cost center or cost centers of the main provider.

Paragraph (d) of § 413.65 was proposed to be retitled ''Requirements applicable to all facilities or organizations'' and, as indicated by its revised title, would set forth those core requirements that any facility or organization would have to meet to qualify for provider-based status.

We proposed to delete from this paragraph (d) the requirements in existing paragraphs (d)(2) and (d)(3) relating to operation under the ownership and control of the main provider and administration and supervision because we proposed to no longer apply these requirements to on-campus facilities or organizations. These requirements would be moved to paragraph (e) as described below to reflect the proposed limitation of their applicability to off-campus departments. The core requirements for all facilities or organizations, including facilities located on campus, also would not include the requirement regarding location in the immediate vicinity of the main provider (existing § 413.65(d)(7)). Because any facilities or organizations located on the campus of the main provider automatically meet the requirement regarding location in the immediate vicinity (existing § 413.65(d)(7)), the requirement is only of relevance to off-campus facilities or organizations. For clarity, we proposed to relocate the requirement to paragraph (e) as described below.

We also proposed to require, in paragraph (d)(5) of § 413.65, all hospital outpatient departments and hospital-based entities, including those located on campus and those located off the campus of the main provider hospital, to fulfill the obligations currently codified and proposed to be retained at § 413.65(g) in order to qualify for provider-based status. (Fulfillment of these obligations is currently required under § 413.65(g).) As explained further below, we also proposed other changes to paragraph (g).

We did not receive any comments on these proposed changes. Therefore, in this final rule, we are adopting the proposed changes as final.

e. Additional Requirements Applicable to Off-Campus Facilities or Organizations

We recognize that facilities or organizations located off the main provider campus may also be sufficiently integrated with the main provider to justify provider-based designation. However, the off-campus location of the facilities or organizations may make such integration harder to achieve than for on-campus facilities or organizations, and such integration should not simply be presumed to exist. Therefore, to ensure that off-campus facilities or organizations seeking provider-based status are appropriately integrated, in the May 9, 2002 proposed rule, we proposed to retain certain requirements to demonstrate integration that we proposed to remove for on-campus facilities or organizations. These requirements were set forth in proposed new § 413.65(e). The requirements set forth in proposed paragraphs (e)(1), (e)(2), and (e)(3) included the requirements on operation under the ownership and control of the main provider (existing § 413.65(d)(2)), administration and supervision (existing § 413.65(d)(3)), and location (existing § 413.65(d)(7)).

We did not receive any comments on these proposed changes. Therefore, in this final rule, we are adopting the proposed changes as final.

f. Joint Ventures

Consistent with our views as expressed earlier in this preamble regarding the assumption that a higher degree of integration can be presumed for on-campus facilities or organizations and in recognition of the need to promote reasonable cooperation among providers and avoid costly duplication of specialty services, in the May 9, 2002 proposed rule, we proposed to revise the regulations on joint ventures (currently set forth under § 413.65(e)) to limit their scope to facilities or organizations not located on the campus of any potential main provider. Specifically, we proposed to redesignate § 413.65(e) as § 413.65(f) and revise it to state that a facility or organization that is not located on the campus of the potential main provider cannot be considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. We also proposed to make minor changes to the second sentence of the redesignated paragraph (f) to clarify its meaning.

Comment: One commenter noted that proposed § 413.65(f) states that facilities or organizations operated by two or more providers engaged in a joint venture cannot be considered provider-based if they are not located on the campus of the potential main provider. The commenter believed that the rule would be more easily understood if paragraph (f) were revised to state that a facility or organization owned by two or more providers engaged in a joint venture cannot be considered provider-based unless it is located on the campus of at least one of the providers engaged in the joint venture.

Response: We agree that clarification of the joint venture requirements is needed. Therefore, in this final rule we are revising § 413.65(f) to clearly state that, in order for a facility or organization operated as a joint venture to be considered provider-based, it must (1) be partially owned by at least one provider; (2) be located on the campus of a provider who is a partial owner; (3) be provider-based to that one provider whose campus on which the facility or organization is located; and (4) meet all of the requirements applicable to all provider-based facilities and organizations in § 413.65(d). Therefore, to be treated as provider-based, the facility operated as a joint venture must be provider-based to the provider whose campus on which the facility is located, regardless of whether that provider is the majority owner.

For example, if Hospital A owns 60 percent of Facility C and Hospital B owns 40 percent of Facility C, but Facility C is located on the campus of Hospital B, Facility C may only be provider-based to Hospital B.

Comment: One commenter asked if the provider where the service is located has to be the billing provider of the joint venture. The commenter also had questions about the rules concerning public awareness and other criteria as they relate to a joint venture service. The commenter asked whether the facility had to advertise as a joint venture, as a service of the provider where the site is located, or as a service of the billing provider.

Response: As we explained in the response to the previous comment, the facility owned by a joint venture must be provider-based to the provider whose campus on which the facility is located, regardless of whether that provider is the majority owner. The main provider does not have to advertise as a joint venture, but as a facility that is provider-based to the main provider. Accordingly, the services in the facility would be billed using the provider number of the provider whose campus on which the facility is located. (The facility cannot, of course, be provider-based with respect to both hospitals.) In addition, the facility owned by a joint venture must also meet all the requirements applicable to all provider-based facilities in § 413.65(d).

Comment: Some commenters requested that CMS allow facilities owned by a joint venture but not located on a hospital's campus to be considered provider-based. The commenters stated that joint ventures among and between hospitals in rural areas greatly help to improve access to care.

Response: While it is not our intent to limit access to care, we continue to believe that facilities owned by joint ventures that are not located on a main provider's campus do not qualify as provider-based. Thus, we are not adopting the commenter's request.

Accordingly, we are adopting as final the proposed § 413.65(f), with clarifying changes to the criteria for being determined a joint venture as discussed under the responses to comments.

g. Clarification of Obligations of Hospital Outpatient Departments and Hospital-Based Entities

Existing regulations impose specific obligations for hospital outpatient departments and hospital-based entities, but do not specify the sanction that applies if the facility or organization does not fulfill its obligations. To clarify policy on this issue and emphasize the importance of compliance with the requirements in this area, in the May 9, 2002 proposed rule, we proposed to revise existing § 413.65(g) to state that to qualify for provider-based status in relation to a hospital, a facility or organization must comply with these requirements. In regard to these obligations, we proposed to make three changes in existing § 413.65(g). First, we proposed to revise paragraph (g)(1) by deleting the second sentence of that paragraph. In paragraph (g)(2), we proposed to delete the reference to site-of-service reductions and instead refer to more accurately determined physician payment amounts, in order to more accurately describe how payment under the physician fee schedule is determined. In addition, we proposed to revise the first sentence of paragraph (g)(7) to clarify that the notice requirements in it do not apply where a beneficiary is examined or treated for a medical condition in compliance with the antidumping rules in § 489.24. We believed that this clarification was needed because we believe it would be a violation of the antidumping requirements if examination or treatment required under § 489.24 was delayed in order to permit notification of the beneficiary or the beneficiary's authorized representative. Further, we proposed to revise § 413.65(g)(7) to state that notice is required once the beneficiary has been appropriately screened and the existence of an emergency has been ruled out or the emergency condition has been stabilized.

We did not receive any comments on these proposed changes to § 413.65(g)(2) and (g)(7). Therefore, in this final rule, we are adopting the proposed changes as final

With regard to the proposed changes to § 413.65(g)(1), although we stated above that we are planning to finalize EMTALA policy proposed on May 9, 2002 in a separate document to be published shortly, we are adopting as final the proposed change concerning the applicability of EMTALA to provider-based entities located on the hospital main campus. Currently, under § 413.65(g)(1), if any individual comes to any hospital-based entity (including an RHC) located on the hospital main campus and a request is made on the individual's behalf for examination or treatment of a medical condition, the entity must comply with the antidumping rules at § 489.24. We stated in the proposed rule (67 FR 31477) that, since provider-based entities, as defined in § 413.65(b), are not under the certification and provider number of the main provider hospital, this language, read literally, would appear to impose EMTALA obligations on providers other than hospitals, a result that would not be consistent with section 1867 of the Act, which restricts EMTALA applicability to hospitals. To avoid confusion on this point and the extension of EMTALA requirements to other nonhospital providers, we are clarifying at § 413.65(g)(1) that EMTALA applies in this scenario to only those departments on the hospital's main campus that are provider-based. Accordingly, EMTALA does not apply to provider-based entities (such as RHCs) that are either on or off the hospital campus.

Because we received no public comments on this proposed clarification on the applicability of EMTALA to provider-based entitles, we are adopting as final this one change at § 413.65(g)(1) by deleting the second sentence at existing § 413.65(g)(1) that addresses this policy. However, we note again that in this final rule we are not adopting other clarifications in the proposed rule concerning application of EMTALA to provider-based departments, on or off the campus, or any other proposals concerning EMTALA. We received over 600 pieces of correspondence on these subjects. In order to give proper consideration to these comments, we plan to issue a final policy on the EMTALA proposals in a separate document.

h. Management Contracts

Under existing regulations, facilities or organizations operated under management contracts may be considered provider-based only if they meet specific requirements in § 413.65(f) (proposed in the May 2002 proposed rule to be redesignated as § 413.65(h)).

In particular, staff of the facility or organization, other than management staff, may not be employed by the management company but must be employed either by the provider or by another organization, other than the main provider, which also employs the staff of the main provider. Under existing regulations, these requirements apply equally to on-campus and off-campus facilities or organizations.

Consistent with our intent to simplify provider-based requirements for on-campus facilities or organizations, we proposed to restrict the applicability of proposed redesignated paragraph (h) to off-campus facilities or organizations. In addition, we proposed two additional changes that we believe are needed to respond to questions that are raised frequently about the regulation. First, we proposed to specify that a facility or organization operated under a management contract may be considered provider-based only if the main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at 42 CFR Part 414. We did not propose to specify who may employ other support staff, such as maintenance or security personnel, and who are not directly involved in providing patient care, nor did we propose to require licensed professional caregivers such as physicians, physician assistants, or certified registered nurse anesthetists to become provider employees. We also proposed to revise the regulations to clarify at § 413.65(h)(2) that so-called ''leased'' employees (that is personnel who are actually employed by the management company but provide services for the provider under a staff leasing arrangement) are not considered to be employees of the provider for purposes of this provision.

Comment: One commenter supported the proposal eliminating restrictions on management contracts and joint ventures for on-campus facilities. The commenter also supported the modification to the management contract rules applicable to off-campus facilities that requires the main provider to employ only those staff who are directly involved in the delivery of patient care, other than staff who may be paid under the Medicare fee schedule, management staff, and other support staff. Another commenter recommended that CMS limit the management contract restrictions for off campus facilities by allowing the management company to employ at least some of the patient care staff at the facility, as long as the facility remains integrated with, and under the control of, the main provider.

Response: We agree with the commenter who stated that it is appropriate to require the main provider to employ only those staff who are directly involved in the delivery of patient care, other than staff who may be paid under the Medicare fee schedule, management staff, and other support staff. We considered the comment suggesting that the regulations be further changed to allow at least some of these staff to be provided under a management contract. However, we are not adopting this change. We note that the revisions in the proposed rule would have significantly relaxed the requirements relating to management contracts by restricting the scope of those provisions to off-campus facilities and by expanding the range of services that may be furnished under management contracts in those facilities. Under our proposal, even if only the services described in this comment would have to be furnished by the provider, the provider would be permitted to bill as if it delivered the services itself. If we were to further weaken the management contract requirements, this would remove any effective control on such contracts, thereby allowing the provider to claim provider-based payment for a facility with which it has only a contractual relationship. We believe such a tenuous connection between the provider and the facility does not warrant payment for the facility's services as services of an ''integral and subordinate'' part of the provider. Therefore, we are not adopting this comment.

Comment: One commenter recommended that inpatient facilities be exempted from the management contract requirements in proposed § 413.65(h).

Response: We note that our proposed rule accomplished much of what the commenter recommended, in that it would exempt on-campus facilities, including those facilities that treat a patient population made up largely or entirely of inpatients, from the management contract requirements in § 413.65(h). We are adopting this proposal without change in the final rule. However, for the reasons discussed earlier in responding to comments on the scope of the provider-based requirements, we do not believe it would be appropriate to exclude off-campus facilities and organizations from the management contract requirements.

Comment: One commenter recommended that CMS regional offices be authorized to exempt facilities or organizations from the management contract requirements on a case-by-case basis, depending on the circumstance in each case.

Response: We agree that regional offices need to exercise judgment in application of the criteria, but do not agree that the exercise of that judgment should include discretion to entirely waive applicability of a requirement. This could lead to wide variations in the applicability of the provider-based criteria in different areas of the country. Therefore, we are not making any change in the final rule based on this suggestion.

Comment: Some commenters requested clarification of the relationship between provision of services under management contracts and under arrangements of the kind described in section 1861(w)(1) of the Act. The commenters further recommended that proposed § 413.65(i), which states that a facility or organization cannot qualify for provider-based status if all services at the facility are furnished under arrangements, be revised so that it does not apply to on-campus facilities. The commenters expressed concern that if that change is not made, management contracts for on-campus facilities or organizations that are permitted under proposed §§ 413.65(d) and (h) would nevertheless be prohibited by § 413.65(i).

Response: Generally, we believe there is a substantial difference between the use of management contracts to obtain some or all input services needed to operate a health care facility, including not only management but professional and other staffing, security, maintenance, other support services, and the use of section 1861(w)(1) arrangements by a provider to obtain specialized health care services that it does not itself offer, and that are needed to supplement the range of services that the provider does offer its patients. In the first situation, it is possible that all or virtually all services needed to operate a facility could be obtained under contract, resulting in nothing more than a nominal connection between the facility and the provider that claims it as an integral and subordinate part. To prevent a facility operated in this way from inappropriately claiming to be part of a provider, reasonable controls on management contracts are needed. In the latter case, a provider may

legitimately obtain limited specific services under arrangements without sacrificing its ability to function independently as a provider and directly furnish care to its patients.

In this context, we would agree with the commenter that a provider that operates a facility that qualifies legitimately as provider-based may choose to obtain some specialized services for its patients under arrangements without needing to meet the management contract requirements of § 413.65(h) with respect to each individual service. As noted above, these requirements apply to facilities, not to individual services. However, we continue to believe it would be inappropriate for a facility, whether located on or off campus, to evade the provider-based requirements by claiming to provide all of its services under arrangements. Therefore, we are not making further changes to § 413.65(i).

Comment: One commenter stated that CMS' intentions were unclear in the proposed regulations at § 413.65(h)(1) that state, ''Leased employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) are not considered to be employees of the provider for purposes of this paragraph.'' The commenter added that it is unclear if this provision prohibits arrangements under which a management company employs clinical staff paid under a fee schedule that are subsequently leased to the main provider to provide services in the provider-based facility. The commenter suggested that we clarify this language and, in the final rule, state that the exception to the main provider employment requirement for patient care staff that furnish services paid for under a fee schedule also applies to leased employees from a management company.

Response: In the proposed rule, we stated that the main provider is required to employ only those staff who are directly involved in the delivery of patient care other than staff who may be paid under the Medicare fee schedule, management staff, and other support staff. Therefore, the main provider may not use ''leased'' employees if those employees are directly involved in delivering patient care and cannot be paid under the Medicare fee schedule. However, this provision would *not* prohibit arrangements under which a management company employs clinical staff who may be paid under a fee schedule that are leased to the main provider to provide services in the provider-based facility. The management company may otherwise employ and provide the staff who furnishes patient care services that may be paid for by Medicare under a fee schedule. Accordingly, as the commenter recommended, we are clarifying the regulations text to state that, other than staff that may be paid under a Medicare fee schedule, the main provider may not utilize the services of leased employees who are directly involved in patient care in off-campus facilities.

Comment: One commenter stated that the proposed regulation that would require the main provider to employ all staff who ''are directly involved in the delivery of patient care, except for management staff * * *'' is confusing, because in many instances, managers are involved both in management activities and in furnishing direct patient care.

Response: If these managers are also medical professionals who may receive payment for their patient care services under a Medicare fee schedule, they do not need to be employed directly by the main provider.

Comment: Some commenters stated that the prohibition of off-campus management contracts will have harmful consequences, particularly in areas where private hospitals have partnerships with local government to operate off-campus psychiatric facilities in remote, underserved areas. The commenter explained that the county government manages an off-campus psychiatric facility as an inpatient psychiatric unit of a private hospital, and that county employees provide all patient care services in the unit. Although the facility is currently grandfathered under section 404(a) of BIPA, the facility will be unable to qualify for provider-based status when the grandfathering period expires, resulting in a loss of essential mental health services to the surrounding communities. The commenters requested that counties that have partnerships with private entities in order to ensure access to care and meet all other provider-based criteria be exempted from the management contract prohibition.

Response: While we are sympathetic to the needs of the medically underserved, we do not believe the management contract requirements to be overly restrictive. Rather, we believe the employment of the staff of an off-campus facility is a significant factor in determining the degree to which a facility or department is integrated (that is, provider-based) with its parent hospital. This is particularly important in a facility operated under a management contract. Because such a facility already receives management (and typically, many other services and supplies) from the management company, employment of the caregivers by the provider provides a strong link to the provider's other operations and demonstrates that the facility continues, despite the purchase of management services under contract, to be an integral and subordinate part of the provider. As such, we do not believe that it is appropriate to exempt any off-campus facilities from the management contract requirement.

Accordingly, we are adopting as final the proposed § 413.65(h) with one change to paragraph (h)(1) to clarify use of leased employees by a provider as discussed in the response to comments.

i. Inappropriate Treatment of a Facility or Organization as Provider-Based

Below we describe the steps that we would take if we discover that a facility is billing as provider-based without having requested a determination or having submitted a complete attestation regarding provider-based status as described earlier, or if the facility received a provider-based determination but the main provider did not inform CMS of a subsequent material change that affected the provider-based status of its facility.

(1) Inappropriate billing

The existing regulations at § 413.65(i) state that if we discover that a provider is billing inappropriately, we will recover the difference between the amount of payments that actually were made and the amount of payments that CMS estimates should have been made in the absence of a determination of provider-based status. Existing § 413.65(j)(2) states that we would adjust future payments to estimate the amounts that would be paid, in the absence of a provider-based determination, if all other requirements for billing are met. In addition, existing § 413.65(j)(5) describes a procedure under which CMS would continue payments to a provider for services of a facility or organization that had been found not to be provider-based, at an adjusted rate calculated as described in existing paragraph (j)(2), for up to 6 months in order to permit the facility or organization adequate time to meet applicable enrollment and other billing requirements. While CMS is not legally obligated to continue payments in this matter, we believe it would be appropriate to do so, on a time-limited basis, to allow for an orderly transition to either provider-based or freestanding

status for the facility and to avoid disruption in the delivery of services to patients, particularly Medicare patients, who may be relying on the facility for their medical care.

In the May 9, 2002 proposed rule, we proposed to adopt a policy concerning recoupment and continuation of payment that closely parallels the policy stated in existing regulations at § 413.65(j). Under proposed § 413.65(j)(1), if CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request an advance determination of provider-based status from CMS under proposed § 413.65(b)(3), and CMS determines that the facility or organization did not meet the requirements for provider-based status under proposed § 413.65(d) through (i), as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS would take several actions. First, we proposed to issue notice to the provider, in accordance with proposed paragraph (j)(3), that payments for past cost reporting periods may be reviewed and recovered as described in proposed paragraph (j)(2)(ii), that future payments for services in or at the facility or organization will be adjusted as described in proposed paragraph (j)(4), and that continued payments to the provider for services of the facility or organization will be made only in accordance with proposed paragraph (j)(5). In addition, we proposed (proposed § 413.65(j)(1)(ii)) that CMS would, except for providers protected under section 404(a) or (c) of BIPA (implemented at § 413.65(b)(2) and (b)(5)) or the exception for good faith effort at existing § 413.65(i)(2) and (i)(3)), recover the difference between the amount of payments that actually was made to that provider for services at the facility or organization and an estimate of the payments that CMS would have made to that provider for services at the facility or organization in the absence of compliance with the requirements for provider-based status. We proposed to make recovery for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. Also, we proposed to adjust future payments to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

Recovery of past payments would be limited in certain circumstances. If a provider did not request a provider-based determination for a facility by October 1, 2002, but is included in the grandfathering period under § 413.65(b)(2), we proposed to recoup all payments subject to the reopening rules at §§ 405.1885 and 405.1889, but not for any period before the provider's cost reporting period beginning on or after July 1, 2003.

Comment: One commenter stated that, under current policies, teaching hospitals may claim the time residents spend training at freestanding facilities (known as ''nonhospital sites'') only when there is a written agreement between the hospital and the nonhospital site. No written agreement is needed if the site is provider-based. The commenter asked that if CMS determines that a facility does not meet the provider-based rules, the indirect medical education (IME) payments that were received by the teaching hospital should not be affected.

Response: If CMS determines that a provider, whether teaching or nonteaching, is inappropriately receiving payment in a facility since the facility is determined not to be provider-based, CMS would take several actions, including, as described under § 413.65(j)(3), reviewing payments for past cost reporting periods in order to recover the difference between the amount of payment that was made to the provider and an estimate of payments that CMS would have made had the facility not been provider-based. It is conceivable that overpayments may have been made, not only for IME but also for direct GME, to a teaching hospital that incorrectly treated a facility as provider-based, and, as such, we would recover an amount of payment for both IME and direct GME that would otherwise not have been received by the hospital had the facility been freestanding.

(2) Good Faith Effort

We proposed to retain the existing exception for good faith effort (proposed redesignated § 413.65(j)(2)). Under this exception, we specified that we would not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001 (the effective date of the existing provider-based regulations for providers not grandfathered under § 413.65(b)(2)) if during all of that period—

- The requirements regarding licensure and public awareness at § 413.65(d)(1) and proposed redesignated (d)(4) were met;
- All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and
- All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described at § 413.65(g)(2).

Under § 413.65(j)(5), we proposed that CMS would continue payment to a provider for services of a facility or organization for a limited period of time, in order to allow the facility or organization or its practitioners to meet necessary enrollment and other requirements for billing on a freestanding basis. Specifically, the notice of denial of provider-based status sent to the provider would ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, as to whether the provider intends to seek an advance determination of provider-based status for the facility or organization, or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services as a freestanding facility.

If the provider indicates that it will not be seeking an advance determination or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payments under proposed paragraph (j)(5) would end as of the 30th day after the date of notice. If the provider indicates that it will be seeking an advance determination, or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization would continue, at the adjusted amount described in proposed paragraph (j)(4) for as long as is required for all billing requirements to be met (but not longer than 6 months).

Continued payment would be allowed only if the provider or the facility or organization or its practitioners submits, as applicable, a complete request for an advance provider-based determination or a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization or its practitioners furnishes all other information needed by CMS to process the request for provider-based status or, as applicable, the enrollment application and verify that other billing requirements are met. If the necessary applications or information are not provided, CMS would terminate all payment to the

provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

As clarified in § 413.65(o) of this final rule, we would not resume provider-based payment to such a facility or organization based on an attestation of compliance. On the contrary, if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in § 413.65(b)(2), for cost reporting periods starting on or after July 1, 2003), CMS will not treat the facility or organization as provider-based for payment until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under Part 413.

Comment: One commenter suggested that, given the complexities surrounding the provider-based rules and the delays in implementing the regulations and establishing a uniform process, the final rule should provide that any provider that complies with the good faith exception under § 413.65(j)(2) should also not be subject to any retroactive recoupment of payments under proposed paragraphs (j) and (k).

Response: The regulations at § 413.65(j)(2) state that recovery of overpayments will not be made for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if the provider made a good faith effort to treat its facilities as provider-based during all that period. This good faith exception was originally included in the April 7, 2000 regulations (originally applicable to periods before October 10, 2000, the original effective date of the provider-based regulations, but subsequently delayed to January 10, 2001).

We believe a good faith exception is appropriate for cost reporting periods beginning before January 10, 2001, when the provider-based regulations first became effective, since it would protect providers that were unaware of the new regulations, yet operated facilities that met a minimal threshold for integration. However, CMS has now published two proposed rules and one final rule on provider-based status, has published ''Qs and As'' on its website, and has consulted extensively with the hospital industry through teleconferences and meetings. Given the publicity that the provider-based regulations have received and the latest delayed effective date of these rules, we do not believe it is appropriate to extend the scope of the good faith exception.

Accordingly, we are adopting the proposals discussed above as final. In addition, we are revising section 413.65(j)(2)(ii) to refer to ''billed with the correct site-of-service'' rather than ''site-of-service indicator'', for consistency with the revision to § 413.65(g)(2) described above.

j. Temporary Treatment as Provider-Based and Correction of Errors

Under proposed revised § 413.65(k), we proposed to specify the procedures for payment for the period between the time a request is submitted until a provider-based determination is made, and the steps we would take if we discover that a facility for which a provider previously received a provider-based determination no longer meets the requirements for provider-based status.

First, we proposed that, if a provider submits a complete request for a provider-based determination for a facility that has not previously been found by CMS to have been inappropriately treated as provider-based under proposed revised § 413.65(j), the provider may bill and be paid for services at the facility as provider-based from the date of the application until the date that we determine that the facility or organization does not meet the provider-based rules under § 413.65. If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete request for a provider-based determination was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. We indicated that we would consider a request ''complete'' only if it included all information we need to make an advance determination of provider-based status under § 413.65(b)(3).

Second, similar to what we specify in existing § 413.65(k), if we determine that a facility or organization that previously received a provider-based determination no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider reported to CMS under § 413.65(c), treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

Third, if we determine that a facility or organization that had previously received a provider-based determination no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS, as required under § 413.65(c), we proposed to take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in proposed paragraphs (j)(3), (j)(4), and (j)(5). In short, we would treat such cases in the same way as if the provider had never obtained an advance determination. However, with respect to recovery of past payments for providers included in the grandfathering provision at proposed revised § 413.65(b)(2), we proposed not to recover payments for any period before the provider's first cost reporting period beginning on or after July 1, 2003.

Also, we proposed that, as under regulations currently in effect, the exception for good faith concerning recovery of overpayments under proposed revised §§ 413.65(j)(2) described above would only apply to any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001.

Comment: One commenter requested that provider-based payment for services of a facility be allowed to continue while the facility is challenging any determination that it is not provider-based.

Response: As we explain in the proposed revised regulations at § 413.65(k), provider-based payment for services at a facility will continue until the date that CMS determines that the facility does not meet the provider-based rules. Once a determination concluding that a facility does not meet the provider-based rules is made, we believe it is inappropriate to continue paying for services at that facility as provider-based. Then, depending upon a number of factors, including whether the facility had previously been determined by CMS to be provider-based and whether the loss of provider-based status resulted from a material change that was or was not reported to CMS, CMS will take actions with respect to recovery of overpayments and continuation of payments at the appropriate nonprovider-based reduced rate, as described in the proposed revised § 413.65(j).

Comment: One commenter noted that proposed paragraph (k) contains some rules applicable to facilities for which there has not been a previous

determination of provider-based status (paragraph (k)(1)) and others that apply to facilities for which such a determination has been made (paragraphs (k)(2) and (k)(3)). The commenter believed these rules would be more clearly understood if the rules for each situation were stated in separate paragraphs.

Response: We agree with the commenter. In this final rule, we are placing the text of proposed paragraph (k)(1) concerning facilities for which there has been no previous determination in new paragraph (k), and the text of proposed paragraphs (k)(2) and (k)(3) concerning facilities for which previous determinations have been made in paragraph (l). Proposed sections (l) through (n) are being redesignated as paragraphs (m) through (o).

In addition, as noted earlier in this preamble, we state in § 413.85(o) of this final rule that, effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in § 413.85(b)(2), for cost reporting periods starting on or after July l, 2003), if a facility or organization previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS, CMS will not treat the facility or organization as provider-based for payment until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under Part 413.

Comment: Regarding the references in paragraphs (k)(1) and (k)(2) of proposed § 413.65 (to be redesignated as (l)(2) and (l)(3), as explained above) to reporting of material changes in the relationship between a provider and a facility or organization that had been found to be provider based, one commenter recommended that the term ''material change'' be defined more specifically, to give providers more direction as to what events to report. The commenter believed a material change should be defined as including only ''a change of ownership, adoption of a new management contract for an off-campus department of a provider or a provider-based entity, change to an off-campus location, or a change in licensure status.''

Response: We share the commenter's belief that the events listed would be considered material changes. However, we do not agree that the term ''material change'' should include only these events. On the contrary, other types of occurrences, such as formation of a separate medical staff for the facility or organization or discontinuation of a service on the main provider's campus that would prevent referral of patients from the facility organization to the main provider would also represent material changes. Because we believe limiting the definition of the term ''material change'' as suggested by the commenter would inappropriately restrict the range of events to be reported, we are not adopting this comment.

Comment: One commenter recommended that reporting of material changes not be required for on-campus facilities. The commenter believed this reporting is unnecessary because adequate safeguards are already built into the provider enrollment requirements.

Response: Several of the kinds of changes noted in response to the preceding comment, relating to the integration of clinical services of the facility or organization with those of the main provider, are not subject to any mandatory reporting under the provider enrollment process but could affect provider-based status. Therefore, we are not making any change in the final rule based on this comment.

Comment: One commenter noted that, in the preamble to the proposed rule, CMS states that there would be '' * * * a delay in the effective date for any facility that is found not to meet the provider-based criteria following a previous advance determination, if the reason the provider-based criteria are not met is a material change in the provider-facility relationship that was properly reported to CMS. The removal of provider-based status would be effective following notification of the redetermination, but not less than 6 months after the date of notification'' (67 FR 31483). The commenter pointed out that this minimum 6-month compliance period is not included in the proposed § 413.65(k)(2). Rather, this regulation states that under these circumstances, provider-based status ''ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.'' The commenter requested that CMS revise § 413.65(k)(2) to reflect the minimum 6-month compliance period.

Response: We agree that the language quoted by the commenter from page 31483 of the preamble to the proposed rule is inconsistent with the language in the proposed regulations text. While this language is consistent with the current policy as stated in existing § 413.65(k), the inclusion of the language on page 31483 of the proposed rule was inadvertent on our part. We note that the correct proposed policy, which correctly *mirrors* the proposed regulation text at § 413.65(k)(2), is stated on page 31487 of the proposed rule. Specifically, we state that ''if we determine that a facility of organization that had previously received a provider-based determination no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider reported to CMS under § 413.65(c), treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.'' We did not intend to propose to allow a 6-month grace period before a facility's status as provider-based would be revoked.

While we regret the confusion caused, we are not adopting the commenter's request regarding a 6-month grace period prior to removal of a provider-based status designation, since we do not believe it would be appropriate to provide for payment to the provider as provider-based for a period for which the provider was clearly not provider-based. While we do not plan to recover overpayments from a facility or organization that no longer qualifies as provider-based if the provider reported a material change in the relationship between the provider and the facility or organization, CMS retains the authority to recoup overpayments and apply civil monetary penalties if a provider is in violation of section 1128A or 1128B of the Act.

Accordingly, we are adopting our proposals as final with the following changes: We are reorganizing the text of proposed § 413.65(k) into new paragraphs (k) and (1), without substantive change, to distinguish the rules applicable to facilities for which there has been no previous determination from those that apply to facilities for which a previous determination has been made. Proposed sections (l) through (n) are being redesignated as paragraphs (m) through (o).

k. Technical Amendments

We proposed to correct a typographical error in the heading of paragraph (m) of § 413.65 (redesignated as paragraph (n) in this final rule) so that it reads ''FQHCs and ''look alikes' ''.

In paragraph (n) of § 413.65 (redesignated as paragraph (o) in this final rule), we proposed to add a cross-reference to the requirements for

provider-based status described in paragraph (b), for purposes of specifying the effective date of provider-based status.

We did not receive any public comments on these technical amendments and are adopting them as final without change except for the redesignation of paragraph codes indicated above.

L. CMS Authority Over Reopening of Intermediary Determinations and Intermediary Hearing Decisions on Provider Reimbursement

Our existing regulations provide various means for the reopening and revision of an intermediary determination or an intermediary hearing decision on provider reimbursement by the fiscal intermediary or the intermediary hearing officer(s) responsible for the determination or the hearing decision, respectively. (In this discussion, we will use the term ''intermediary'' to refer to, as applicable, the intermediary responsible for an intermediary determination (see §§ 405.1801(a) and 405.1803) or the intermediary hearing officer or panel of intermediary hearing officers responsible for an intermediary hearing decision (see §§ 405.1817 and 405.1831.)) Section 405.1885(a) provides that an intermediary ''may'' reopen an intermediary determination or an intermediary hearing decision, on its own initiative or at the request of a provider, within 3 years of the date of the notice of the intermediary determination or intermediary hearing decision. However, while § 405.1885(a) provides the intermediary with some discretion about whether to reopen an intermediary determination or an intermediary hearing decision, we have always considered the intermediary's discretion to be limited by any directives that we may issue. Thus, although § 405.1885(a) provides that the intermediary ''may'' reopen, that provision neither states nor implies that the Secretary lacks authority to direct the intermediary to reopen or not reopen a specific matter. Furthermore, we have prescribed, in Medicare Provider Reimbursement Manual, Part I (''PRM''), section 2931.2, criteria that guide the intermediary's reopening actions under § 405.1885(a) in the absence of a particular CMS directive. Also, given that the intermediaries are our (CMS') contractors, we have always believed that, under basic principles of agency law, we have inherent authority to direct the actions of our own agents with respect to reopening matters under § 405.1885(a), just as for any other aspect of program administration. (See also 42 U.S.C. 1395h and 1395kk(a); and 42 CFR 421.1(c), 421.5(b), 421.100(f), 421.124(a), and 421.126(b).)

Under § 405.1885(b), an intermediary determination or an intermediary hearing decision ''must be reopened and revised by the intermediary if, within the aforementioned 3-year period, the Centers for Medicare & Medicaid Services notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Centers for Medicare & Medicaid Services.'' We have always considered our notice, which is a precondition of mandatory intermediary reopening under § 405.1885(b), to be one in which we explicitly direct the intermediary to reopen. We have never considered a notice or other document from us that only states or implies that an intermediary determination or an intermediary hearing decision is inconsistent with law, regulations, CMS ruling, or CMS general instructions, sufficient to require intermediary reopening under § 405.1885(b). Moreover, our understanding has always been that the phrase ''law, regulations, or general instructions'' in § 405.1885(b) refers to the legal provisions in effect, as we understood such legal provisions at the time the intermediary rendered the determination or hearing decision. Conversely, we have never considered changes in, or judicial explications of, ''law, regulations, or general instructions,'' that occur after the intermediary rendered the determination or hearing decision, sufficient to require intermediary reopening under § 405.1885(b). Also, § 405.1885(b) refers to the Secretary's agreement with an intermediary; we believe such agreement requires the intermediary to apply the law, regulations, CMS rulings, and CMS general instructions in effect, as we understood such legal provisions when the intermediary determination or hearing decision was rendered. Accordingly, we have not instructed intermediaries to reopen and recover reimbursement, or to reopen and award additional reimbursement, due to a subsequent change in law or policy, whether the subsequent change is made in response to judicial precedent or otherwise.

Section 405.1885(c) provides: ''Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.'' We have always interpreted § 405.1885(c) to provide that authority to reopen an intermediary determination or an intermediary hearing decision is vested exclusively with the responsible intermediary, as distinct from the Provider Reimbursement Review Board (PRRB) and the CMS Administrator (in the context of reviewing PRRB decisions (see § 405.1875)) which may not reopen an intermediary determination or hearing decision and may not review an intermediary's denial of reopening. However, we have never considered the intermediary's authority to reopen an intermediary determination or hearing decision, which is exclusive under § 405.1885(c) only as to the PRRB and the CMS Administrator (in the context of reviewing PRRB decisions), to limit our authority to direct the actions of our agents with respect to reopening matters. (*See Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449, 452–53 (1999)(§ 405.1885(c) divests the PRRB of ''appellate jurisdiction to review the intermediary's refusal'' to reopen, but does not limit the Secretary's authority to direct an intermediary's ''original jurisdiction'' in the reopening area).) As discussed previously, the regulations do not constrain our authority to direct the intermediary to reopen or not reopen a specific matter; instead, we have placed generally applicable limits on the intermediary's discretion through the reopening criteria prescribed in section 2931.2 of the PRM. In addition, we have always believed that, under basic principles of agency law, the intermediary's discretion over a particular reopening matter is no less circumscribed by any CMS directives that may be issued than would be the case for any other aspect of program administration.

Two recent court decisions conflict with our longstanding interpretation of the forgoing provisions of the reopening regulations. In *Monmouth Medical Center* v. *Thompson,* 257 F.3d 807 (D.C. Cir. 2001), the court found that a statement in a CMS ruling, changing CMS' interpretation of the statute in response to circuit court precedent, constituted a directive to the intermediary under § 405.1885(b) to reopen, notwithstanding an explicit directive in the CMS ruling that the change in interpretation was to be applied only prospectively. The court ordered the intermediary to reopen over the Secretary's objection. We disagree with the court's decision, which we believe does not comport with our settled interpretation (discussed above) of § 405.1885(b). Therefore, in the May 9, 2002 proposed rule, we proposed to revise § 405.1885(b) to make clear that,

in order to trigger the intermediary's obligation to reopen, our notice to the intermediary must explicitly direct the intermediary to reopen based on a finding that an intermediary determination or an intermediary hearing decision is inconsistent with the law, regulations, CMS ruling, or CMS general instructions in effect, and as we understood those legal provisions, at the time the determination or decision was rendered. We also proposed to clarify § 405.1885 to reflect our longstanding interpretation (discussed above) that a change of legal interpretation or policy through regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

The *Monmouth Medical Center* decision was followed in *Bartlett Memorial Medical Center* v. *Thompson,* 171 F. Supp. 2d 1215 (W.D. Okla. 2001). In a subsequent order in the *Bartlett Memorial Medical Center* case, the court concluded that a CMS ruling, which prohibited intermediary reopening on a particular reimbursement issue, improperly interfered with the intermediary's discretion under § 405.1885(c) over provider requests for reopening under § 405.1885(a). Accordingly, the court ordered the intermediary to act on the provider reopening requests without regard to the CMS ruling or any other involvement of the Secretary. We disagree with the court's decision, which we believe is contrary to our settled interpretation (discussed above) of §§ 405.1885(a) and (c). We believe the court's decision is also inconsistent with our inherent authority to direct the activities of our contractor-agents, the fiscal intermediaries, with respect to particular reopening matters, just as with any other aspect of program administration. Therefore, we proposed, in a new paragraph (e) of § 405.1885 (the existing paragraph was proposed to be redesignated as paragraph (f)), to clarify that, notwithstanding an intermediary's discretion to reopen or not reopen under paragraphs (a) and (c) of § 405.1885, we may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section.

We received a number of comments regarding the proposed revisions to the reopening rules. The commenters largely opposed the our proposed revisions to § 405.1885. Their comments and our responses are as follows.

Comment: A fiscal intermediary asked if CMS was implicitly proposing to make all reopening decisions. According to another commenter, the proposed rule would enhance CMS' control over the reopening process by displacing the intermediary's role as the evaluator of the merits of reopening matters.

Response: The revisions to the reopening regulations are not intended to change the usual allocation of responsibilities between CMS and the fiscal intermediaries, which leaves most reopening decisions to the intermediaries. We are simply clarifying the regulations to reflect our longstanding interpretations, not revamping settled reopening policies and procedures.

As the courts have recognized, the reopening regulations are based on the Secretary's general rulemaking authority. (See *HCA Health Servs. of Oklahoma, Inc.* v. *Shalala,* 27 F.3d 614, 618 (D.C. Cir. 1994).) In the past, our main role has been to provide general guidance regarding the reopening regulations, such as the instructions included in Chapter 29 of the Medicare Provider Reimbursement Manual, Part 1 (''PRM''). The intermediaries have typically decided, without consulting with us, whether to reopen specific intermediary determinations or hearing decisions in accordance with §§ 405.1885(a) and (c) and the PRM. Of course, our authority to require intermediary reopening has been recognized specifically in § 405.1885(b). In certain instances, we have directed the intermediaries' reopening actions on a recurring reimbursement issue, such as the ''disproportionate share'' issue addressed in HCFA Ruling 97–2 (February 27, 1997). On occasion, we have instructed an intermediary to reopen a specific matter, such as in implementing the settlement of an administrative appeal or a lawsuit.

The foregoing allocation of responsibilities is not altered by the revisions to the reopening regulations. Rather, we are clarifying the regulations to comport with our longstanding interpretation that the intermediary's duty to reopen a determination or decision under § 405.1885(b) arises only if we specifically direct it to reopen in order to ensure consistency with a legal provision, as we understood such provision when the determination or decision was issued. Moreover, revised § 405.1885(e) simply clarifies our interpretation that the intermediary's discretion whether to reopen under §§ 405.1885(a) and (c) is subject to CMS' authority to direct the ''original jurisdiction'' of its own contractor over reopening matters, as with any other area of program administration. Thus, while the intermediaries will continue to decide most reopening matters without consulting with CMS, § 405.1885(e) reflects our authority to direct the intermediaries as we deem necessary and appropriate.

Comment: Two commenters stated that the reopening process has been the province of the intermediary. According to the commenters, the proposed changes to § 405.1885(e) would give CMS the sole authority to decide reopening matters that were formerly the intermediary's responsibility, which would eliminate the discretionary character of intermediary reopening decisions. Thus, the commenters concluded, intermediary reopening denials would be subject to PRRB and judicial review despite the Supreme Court's decision in *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449 (1999).

Response: We disagree with the commenters' assertion that the proposed revisions to the reopening regulations would affect the reviewability of intermediary reopening denials. As discussed above, although the intermediaries have typically decided, without consulting with CMS, whether to reopen specific intermediary determinations or hearing decisions, the contractors' reopening actions have always been subject to the general guidance and any particular directives issued by CMS. Again, the respective roles of CMS and the intermediaries are simply not changed by the revisions to the reopening regulations. Since the intermediaries will continue to decide most reopening matters without consulting with CMS, reopening decisions will typically reflect the usual exercise of the intermediary's unreviewable discretion.

Although the revisions to the reopening regulations pertain to different issues than those resolved by the Supreme Court's *Your Home Visiting Nurse* decision, we believe that the revised regulations are consistent with the Court's decision and related precedent. The Supreme Court held that an intermediary's rejection of a provider's reopening request is not reviewable by the PRRB or the Federal courts. *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 452–58. The revisions to the reopening regulations do not address or affect the reviewability of intermediary reopening denials. Rather, the revisions clarify our settled policies regarding the intermediary's original jurisdiction over the reopening question. *Id.* at 453. Specifically, the revisions to

§ 405.1885(b) clarify our longstanding view that intermediary reopening is required only if we specifically mandate reopening in order to ensure consistency with a legal provision, as we understood such provision when the intermediary determination or decision was issued. Furthermore, as proposed, revised § 405.1885(e) clarifies our understanding that the intermediary's discretion whether to reopen under §§ 405.1885(a) and (c) is subject to our authority to direct the original jurisdiction of our contractor over reopening matters, as with any other area of program administration.

We recognize that the Supreme Court, in rejecting mandamus relief in *Your Home Visiting Nurse* for lack of a ''clear nondiscretionary duty,'' reasoned that § 405.1885(a) and PRM section 2931.2 permit but do not require reopening. *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 456–57. (However, we note that intermediary discretion did not figure in the Court's rejection of PRRB and Federal question jurisdiction over intermediary reopening denials. *Id.* at 452–56.) Given that the intermediaries will decide most reopening matters without consulting us, as in the past, such decisions will still be based on the discretionary provisions of § 405.1885(a) and PRM section 2931.2 and thus *Your Home Visiting Nurse* will be squarely on point.

We believe that a reopening denial is no less discretionary—and unreviewable under Your *Home Visiting Nurse* and related precedent—when we mandate the intermediary's action. Notably, in both *Monmouth Medical Center* and *Bartlett Memorial Medical Center,* the courts rejected PRRB and federal question jurisdiction over the prohibition of intermediary reopening included in HCFA Ruling 97–2. *Monmouth Medical Center* v. *Thompson,* 257 F.3d at 810–13; *Bartlett Memorial Medical Center.* v. *Thompson,* 171 F. Supp. 2d at 1220–22. Mandamus relief was ordered in both cases, based on the courts' finding that the Ruling engendered a clear nondiscretionary duty to reopen under § 405.1885(b). However, the Supreme Court has consistently held that reopening denials are ''committed to agency discretion by law' within the meaning of the Administrative Procedure Act, and hence unreviewable.'' *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 457 (following *ICC* v. *Locomotive Engineers,* 482 U.S. 270, 282 (1987)). We believe that, under basic principles of agency law, it would be incongruous to suppose that reopening denials required by the principal, CMS, are somehow less discretionary than denials based on the judgment of our agents, the fiscal intermediaries. (See *ICC* v. *Locomotive Engineers,* 482 U.S. at 277B84 (despite statutory authorization of reopening for material error, Interstate Commerce Commission's refusal to reopen is committed to the agency's unreviewable discretion by law).)

Comment: A commenter stated that CMS should not restrict intermediaries' ability to reopen cost reports when they find it fair and appropriate to do so. The commenter explained that, in dealing with thousands of providers throughout the country, the intermediaries encounter numerous factual scenarios that different contractors might treat through varying means. The commenter concluded that, if a statute or regulation is ambiguous and CMS has not issued a policy statement on an issue, the intermediaries should be free to decide whether to reopen the matter and make revisions deemed suitable.

Response: In the absence of a CMS directive, intermediary reopening decisions have been guided by the criteria of ''new and material evidence,'' ''clear and obvious error,'' and consistency with a legal provision. (See PRM section 2931.2.) The revisions to the reopening regulations do not change the PRM guidelines. Instead, revised § 405.1885(e) clarifies our settled view that we have full authority to direct an intermediary to reopen, or not to reopen, under §§ 405.1885(a) and (c) based on the PRM reopening criteria.

However, as explained above, the intermediaries will continue to decide most reopening matters without consulting with CMS. In cases where we have not interpreted a statute or regulation or issued a policy statement on a reimbursement issue, the intermediaries will typically be free to decide whether to reopen the matter. Although the different intermediaries will be guided by the reopening guidelines in the PRM, different contractors may reach varying decisions on whether to reopen, or how to revise, a determination or decision. The traditional flexibility and variability of intermediary reopening decisions will not change as a result of the revisions to the reopening regulations.

Comment: A commenter stated that if CMS publishes a policy statement clarifying a particular Medicare issue, the intermediaries should have the ability to reopen cost reports to ensure that all providers are treated uniformly. Another commenter stated that it is not reasonable to expect intermediaries to apply rulings retroactively in some instances.

Response: We believe that an important component of a new reimbursement policy is the policy's scope of applicability. Given that Medicare is a uniform nationwide program, we typically do not leave to the discretion of the intermediaries questions about the scope of applicability of our reimbursement policy or policy clarification. Instead, a CMS regulation or policy guideline on a reimbursement issue usually includes an effective date. New reimbursement policies normally apply on a prospective-only basis. (See *Bowen* v. *Georgetown University Hospital,* 488 U.S. 204, 208–16 (1988) (Medicare statute does not permit retroactive rulemaking).) The alternative suggested by the commenter, of letting the intermediaries determine through reopening the scope of applicability of a new CMS reimbursement policy, would undermine the interests of nationally uniform program administration. Also, if the intermediaries were to reopen and apply a reimbursement policy that was not in place when payment was determined originally, such reopenings might involve impermissible retroactive rulemaking.

Comment: A commenter asserted that the proposed revisions to § 405.1885(b) would inappropriately expand CMS' authority by permitting the agency to order an intermediary to disregard a judicial decision holding a policy void *ab initio,* on the theory that CMS understood the disputed legal provision differently when the intermediary determination was rendered. Thus, the commenter concluded, the proposal violates fundamental principles of separation of powers.

Response: The revisions to § 405.1885(b) do not expand our reopening authority. Rather, revised paragraph (b)(1) clarifies our settled interpretation that an intermediary's duty to reopen a determination or decision under § 405.1885(b) arises only if we specifically direct it to reopen in order to ensure consistency with a legal provision, as we understood such provision when the determination or decision was issued.

We did not propose paragraph (b)(1) as a means of sidestepping a judicial decision holding a reimbursement policy void *ab initio,* on the theory that we understood the disputed legal provision differently when the intermediary determination at issue in the lawsuit was rendered. If a provider secures a final, nonappealable judgment rejecting a reimbursement policy, we would certainly comply with such a court judgment for the provider's fiscal

period at issue in the lawsuit— even if we had a different understanding of the law when the intermediary determination at issue in the case was rendered. Given our compliance with the final, nonappealable judicial decision, there clearly would be no separation of powers problem.

The commenter may be assuming that reopening is necessary for the implementation of a final, nonappealable judgment. That would be a debatable assumption for a number of reasons. For example, we would be required to redetermine reimbursement in accordance with a final, nonappealable court judgment for the fiscal period at issue in the lawsuit, even if the 3-year period for reopening the intermediary determination at issue in the case had expired long ago. Also, we often implement final adverse judgments and lawsuit settlement agreements outside the reopening process. Instead of reopening the reimbursement matter and issuing a revised notice of program reimbursement (see §§ 405.1801(a), 405.1803, and 405.1889), we may simply recalculate reimbursement in accordance with the final court decision or settlement agreement, and issue an implementation notice detailing the reimbursement effect of the court judgment or settlement agreement.

However, the comment does indicate that the proposed rule was susceptible to the interpretation that CMS would be precluded from requiring the reopening of a particular intermediary determination or decision in order to implement a specific final agency decision (see §§ 405.1833, 405.1871(b), 405.1875, and 405.1877(a)); a particular final, nonappealable court judgment; or a specific agreement to settle an administrative appeal or a lawsuit. In order to allay the commenter's concern and make explicit our authority to use reopening procedures in such circumstances, as we deem appropriate, we have added a new paragraph (b)(3) to proposed § 405.1885(b). Paragraph (b)(3) states that notwithstanding paragraph (b)(1)(i) of this section, CMS may direct the intermediary to reopen a particular intermediary determination or intermediary hearing decision in order to implement, for the same intermediary determination or intermediary decision— (1) a final agency decision under §§ 405.1833, 405.1871(b), 405.1875, or 405.1877(a); (2) a final nonappealable court judgment; or (3) an agreement to settle an administrative appeal or a lawsuit.

Comment: According to one commenter, the inclusion of the condition ''as CMS understood those legal provisions, at the time the [intermediary] determination or decision was rendered,'' in the provisions of § 405.1885(b) for mandatory intermediary reopening would give CMS unlimited and standardless discretion whether or not to reopen.

Response: Paragraph (b)(1)(i) does include a guideline for CMS' decision whether to require intermediary reopening under § 405.1885(b). If an intermediary determination or decision is inconsistent with the applicable law, regulations, CMS Ruling, or CMS general instructions in effect, as CMS understood such legal provisions when the intermediary rendered the determination or decision, then CMS may decide to direct the intermediary to reopen and revise the determination or decision. However, we are not required to mandate intermediary reopening in such cases. Thus, given the Supreme Court's decisions in *Your Home Visiting Nurse* and *ICC* v. *Locomotive Engineers,* if CMS directs the intermediary to not reopen, our instruction and the intermediary reopening denial are committed to the agency s unreviewable discretion under the Administrative Procedure Act, 5 U.S.C. 701(a)(2).

Moreover, we believe that our longstanding practice of looking to the law in effect, as we understood the law, when the intermediary determination or decision was rendered, is supported by analogous principles followed by the courts. For example, it is settled that '' 'the legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place.' '' *Landgraf* v. *USI Film Products,* 511 U.S. 244, 265 (1994) (citation omitted). Also, the courts consistently hold that past judicial decisions, even if subsequently deemed erroneous, are *res judicata* and should not be resurrected and redecided. (See, *Federated Department Stores, Inc.* v. *Moitie,* 452 U.S. 394, 398 (1981).) Of course, this principle works both ways: if a disposition benefiting a claimant becomes final before a contrary decision on the same issue in another case, the claimant is not required to surrender the benefit despite the intervening change in decisional law. (See, *Aaron* v. *Kansas,* 115 F.3d 813, 814 n.1 (10th Cir. 1997).)

Comment: One commenter asserted that when the courts find a CMS policy unlawful, and the agency revises its policy to comport with the courts' decisions, providers should be entitled to reopening and application of the new policy within applicable time limits. According to a hospital system, foreclosing reopening of a matter that was settled inconsistently with decisional law would lead to inconsistent decisions regarding different providers, and have the agency persist in conduct held unlawful by the courts.

Response: We disagree. As proposed, paragraph (b)(2) clarifies our longstanding view that a change of legal interpretation or policy by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or decision under § 405.1885.

The prospect of widespread reopening for application of a new legal interpretation or policy, whether in response to judicial precedent or otherwise, might involve impermissible retroactive rulemaking. (See *Bowen* v. *Georgetown University Hospital,* 488 U.S. at 208–16.) If we were to allow systemic reopening for application of a legal interpretation or policy adopted in response to judicial precedent, our fiduciary responsibilities for the Medicare trust funds would arguably call for similarly widespread reopening when a new legal interpretation or policy is not favored by providers. The result might be a spate of litigation involving alleged retroactive rulemaking and other complex legal issues.

Furthermore, we have not viewed the reopening process as a ready alternative to the mechanism for administrative appeals and judicial review established by the Medicare statute and regulations. Under the statute (section 1878(a) of the Act) and the regulations (§§ 405.1801(a), 405.1803, and 405.1807), an ''intermediary determination'' is, by definition, a ''final determination'' of program reimbursement. We believe that, if a provider does not file a timely appeal of a final determination on a reimbursement issue, there is no right to reopening of that issue in light of judicial decisions in other cases on the same issue. Put simply, reopening is not designed for the revival of stale claims, *Albert Einstein Medical Center.* v. *Sullivan,* 830 F. Supp. 846, 850 (E.D. Pa. 1992), aff'd, 6 F.3d 778 (3d Cir. 1993), or the addition of new claims. *Saint Mary of Nazareth Hospital Center.* v. *Schweiker,* 741 F.2d 1447, 1449 (D.C. Cir. 1984).

In addition, we believe that our longstanding policy of not reopening for application of a new legal interpretation or policy, whether in response to judicial precedent or otherwise, comports with analogous judicial practice. When the Supreme Court decides a legal issue, the Court's ''controlling interpretation of federal law'' applies to ''all cases still open on

direct review,'' *Harper* v. *Virginia Department of Taxation,* 509 U.S. 86, 97 (1993), but ''[n]ew legal principles * * * do not apply to cases already closed.'' *Reynoldsville Casket Co.* v. *Hyde,* 514 U.S. 749, 758 (1995). Thus, while a provider that files a timely appeal may, if it ultimately prevails, be reimbursed differently for an item than providers that do not appeal timely, we do not believe that the decision in the prevailing provider's case should apply to other providers' cost reports that were closed and not appealed timely.

Our settled reopening policy, clarified in § 405.1885(b)(2), also furthers the interests of administrative finality in a program of extraordinary magnitude. For example, there were only 37 fiscal intermediaries in 1997 as compared to approximately 38,000 participating providers. Of course, each provider submits an annual cost report containing thousands of cost items, any one of which may give rise to a reimbursement issue. (See *Athens City Hospital, Inc.* v. *Schweiker,* 743 F.2d 1, 3 (D.C. Cir. 1984) (detailing cost report contents).) We believe it would be unworkable to reopen thousands of final, unappealed cost reports each time a judicial decision calls into question one of our many reimbursement policies. Indeed, the Supreme Court concluded that, ''given the administrative realities we would not be shocked by a system in which underpayments could never be the basis for reopening'' since the ''few dozen fiscal intermediaries often need three years * * * to discover overpayments in the tens of thousands of NPRs that they issue, while each * * * sophisticated Medicare-provider * * * is generally capable of identifying an underpayment in its own NPR within the 180-day time period specified in 42 U.S.C. 139500(a)(3)'' for an appeal to the PRRB. *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 455–56. Thus, instead of the ''persistent'' unlawful conduct suggested by the commenter, we believe that our policy of not reopening closed cost reports in response to decisions in other cases is essential for maintaining administrative finality in a program of extraordinary magnitude that is administered with limited resources.

Comment: A group of health law attorneys recommended that CMS propose more elaborate revisions to the reopening regulations. The commenter saw the need for an orderly process for the correction of factual errors and erroneous interpretations of Medicare law. Also, the commenter recommended that § 405.1885(b) be amended so that CMS must require intermediary reopening for all providers located in the jurisdiction of a court that declares a Medicare policy unlawful. The commenter stated that, in light of the Supreme Court's *Your Home Visiting Nurse* decision, § 405.1885(a) should be revised to require intermediaries to grant provider requests for reopening to correct factual errors and improper application of policy rather than leaving the reopening decision to the intermediaries' discretion. According to the same commenter, the regulations should also detail the circumstances, if any, in which the intermediary may reopen in light of a judicial decision or other change in law. In the same vein, a different commenter stated that some level of materiality should be established so that providers are not confronted with several sets of adjustments for various cost reporting years.

Response: We proposed revisions to the reopening regulations in response to the *Monmouth Medical Center* and *Bartlett Memorial Medical Center* decisions. Our limited purpose was to clarify longstanding interpretations of the reopening regulations, which we believe were misapprehended by the courts.

More elaborate revisions to the reopening regulations are beyond the scope of the proposed rule. In any event, we believe the reopening regulations and related provisions of the PRM provide an orderly process for the correction of factual errors and erroneous interpretations of the law in effect, as we understood the law, when the intermediary determination or decision was rendered. We also believe that the reopening criteria prescribed in PRM section 2931.2 provide the intermediaries with sufficient guidance regarding the materiality of a potential reopening and revision to program reimbursement.

In lieu of the commenter's suggestion that we allow reopening for application of a judicial decision in another case or for some other change in law, we have revised § 405.1885(b) to reflect our longstanding practice of not reopening for application of a new legal interpretation or policy, whether in response to judicial precedent or otherwise. As explained above, we believe this reopening policy avoids retroactive rulemaking problems; comports with analogous judicial practice and the limited nature of the reopening process; and furthers the goals of administrative finality in a program of extraordinary magnitude that is administered with limited resources.

We also do not believe that the Supreme Court's *Your Home Visiting Nurse* decision requires any revision to § 405.1885(a) or any other reopening provision. As discussed above, the Court's rejection of PRRB and Federal court review of intermediary reopening denials continues the ''tradition of nonreviewability * * * [of] refusals to reconsider * * * by agencies as by lower courts; * * * another tradition that [the Administrative Procedure Act,] 5 U.S.C. 701(a)(2) was meant to preserve.'' *ICC* v. *Locomotive Engineers,* 482 U.S. at 282. Thus, we believe *Your Home Visiting Nurse* and related precedent apply equally to intermediary reopening denials directed by CMS and to denials by the intermediary acting alone.

For the reasons discussed above and although the commenters largely opposed our proposed revisions to the reopening provisions, we are finalizing these provisions as proposed with a technical change to § 405.1885(b)(3).

VI. Changes to the Prospective Payment System for Capital-Related Costs

A. Background

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services ''in accordance with a prospective payment system established by the Secretary.'' Under the statute, the Secretary has broad authority in establishing and implementing the capital prospective payment system. We initially implemented the capital prospective payment system in the August 30, 1991 final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

Federal fiscal year (FY) 2001 was the last year of the 10-year transition period established to phase in the prospective payment system for hospital inpatient capital-related costs. Beginning in FY 2002, capital prospective payment system payments were based solely on the Federal rate for the vast majority of hospitals. The basic methodology for determining capital prospective payments based on the Federal rate is set forth in § 412.312. For the purpose of calculating payments for each discharge, the standard Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (Large Urban Add-on, if applicable) × (COLA Adjustment for hospitals located in

Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable)

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year that are specified in § 412.312(c) of existing regulations. (Refer to the August 1, 2001 final rule (66 FR 39910) for a summary of the statutory basis for the system, the development and evolution of the system, the methodology used to determine capital-related payments to hospitals both during and after the transition period, and the policy for providing special exceptions.)

B. New Hospitals

Under the prospective payment system for capital-related costs, at § 412.300(b), a new hospital is defined as a hospital that is newly participating in the Medicare program (under current or previous ownership) for less than 2 years (see 56 FR 43418, August 30, 1991). During the 10-year transition period, under § 412.324(b), a new hospital was exempt from the capital prospective payment system for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Effective with its third cost reporting period, a new hospital was paid under the appropriate transition methodology (either hold-harmless or fully prospective) for the remainder of the transition period. (If the hold-harmless methodology were applicable, hold-harmless payments would be made for 8 years, even if they extend beyond the 10-year transition period, which ended beginning with cost reporting periods beginning during FY 2002.)

This payment provision was implemented to provide special protection to new hospitals during the transition period in response to concerns that prospective payments under a DRG system may not be adequate initially to cover the capital costs of newly built hospitals. These hospitals may not have sufficient occupancy in those initial 2 years and may have incurred significant capital startup costs, so that capital prospective payment system payments may not be sufficient. For instance, hospitals newly participating in the Medicare program may not initially have adequate Medicare utilization. Because capital prospective payment system payments are made on a per discharge basis, a hospital only receives payments for its capital-related costs upon discharge of its Medicare patients. In addition, these hospitals did not have an opportunity to reserve previous years' capital prospective payment system payments to finance capital projects.

While the regulations provided for payments based on a percentage of costs for new hospitals for the first 2 years during the 10-year transition period, no provision was made for new hospitals once the 10-year transition was completed. However, we believe that the rationale for the policy applies equally to new hospitals even after the completion of the 10-year transition period. Accordingly, in the May 9, 2002 proposed rule (67 FR 31488), we proposed, under § 412.304(c)(2), to provide special payment to new hospitals for cost reporting periods beginning on or after October 1, 2002. That is, we proposed to pay new hospitals, as defined under § 412.300(b), 85 percent of their reasonable costs for their first 2 years of operation. Effective with their third year of operation, a new hospital would be paid based on the Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital prospective payment system). We stated that we believe this amendment will provide for more appropriate payments to new hospitals for their capital-related costs since initial capital expenditures may reasonably exceed the capital prospective payment system per discharge payment based on the Federal rate. The capital prospective payment Federal rate is based on industry-wide average capital costs rather than the experience of a new hospital. We believe this policy will allow new hospitals to provide efficiency in the delivery of services and still make reasonable payments for their capital expenditures.

As was the case during the 10-year transition period, the new hospital exemption will only be available to those hospitals that have not received reasonable cost-based payments under the Medicare program in the past, and would need special protection during their initial period of operation. This exemption from the capital prospective payment system for the first 2 years of operation will not apply to a hospital that is ''new'' as an acute care hospital but that has operated in the past (under current or previous ownership) and has an historical Medicare asset base. Furthermore, a hospital that replaces its entire facility (regardless of a change of ownership) will not qualify for the new hospital exemption even though it may experience a significant change in its asset base. Thus, in accordance with § 412.300(b), a new hospital exemption will not apply in the following situations:

- A hospital that builds new or replacement facilities at the same or a new location, even if a change of ownership or a new leasing arrangement is involved;
- A hospital that closes and then reopens under the same or different ownership;
- A hospital that has been in operation for more than 2 years but has been participating in the Medicare program for less than 2 years; or
- A hospital that changes status from a prospective payment system-excluded hospital (paid under the TEFRA methodology) or another hospital prospective payment system (such as the inpatient rehabilitation facility prospective payment system) to a hospital that is subject to the capital prospective payment system for acute care hospitals.

Comment: Three commenters addressed our proposed policy for new hospitals after the 10-year transition period for cost reporting periods beginning on or after October 1, 2002. One commenter asked whether new providers would have the option of electing payment at 100 percent of the Federal rate for their first 2 years of operation rather than the special payment provision of 85 percent of their reasonable costs. Another commenter expressed concern about the negative impact the proposed policy would have on its facility if the policy were applied retroactively, while still another commenter requested that the policy be effective for new hospitals with cost reporting periods beginning on or after October 1, 2001 rather than October 1, 2002.

Response: We agree with the commenter's suggestion that new hospitals (as defined in § 412.300(b)) should have the option of electing payment for their first 2 years of operation through either the special payment provision for new hospitals at 85 percent of their reasonable costs, or beginning immediately to receive payments based on 100 percent of the Federal rate. However, the payment method that the new hospital selects would remain in effect through the hospital's first 2 years of operation; the hospital would not be allowed to revert to the alternate payment method. If 100 percent of the Federal rate is the payment method selected, the new hospital must make the request to the fiscal intermediary in writing by the later of December 1, 2002, or within 60 days of the start of the provider's cost reporting period. We are revising the regulations at § 412.304(c)(2) to reflect this change.

While we are making this change effective for cost reporting periods beginning on or after October 1, 2002, we are not making this change effective for any periods prior to that date because doing so would constitute retroactive rulemaking.

Accordingly, in this final rule, we are adopting as final the proposed regulation change at § 412.304(c), with modifications. In § 412.304(c)(2)(i), we are specifying that a new hospital is paid (1) 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost report ending at least 2 years after the hospital accepts its first patient; or (2) if the new hospital elects, 100 percent of the Federal rate under the capital prospective payment system. If the new hospital elects to be paid 100 percent of the Federal rate, it must make the request to the fiscal intermediary in writing by the later of December 1, 2002, or within 60 days of the start of the provider's cost reporting period. We are specifying that once a new hospital elects to be paid based on 100 percent of the Federal capital prospective payment rate, it may not revert to payment at 85 percent of its allowable Medicare inpatient hospital capital-related costs.

C. Extraordinary Circumstances

When we implemented the capital prospective payment system in FY 1992, a number of commenters requested that we provide for a separate exceptions payment to account for extraordinary circumstances beyond a hospital's control that would require the hospital to make unanticipated major capital expenditures (56 FR 43411, August 30, 1991). In response to the commenters' request, we provided in the regulations at § 412.348(f) that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a flood, a fire, or an earthquake. For more detailed information regarding this policy, refer to the August 30, 1991 **Federal Register** (56 FR 43411).

To clarify that this policy regarding additional payments for extraordinary circumstances also applies to periods beginning on or after October 1, 2001, in the May 9, 2002 proposed rule (67 FR 31489), we proposed to revise § 412.312 by adding a new paragraph (e) to specify that payment is made for extraordinary circumstances as provided for in § 412.348(f) for cost reporting periods after the transition period, that is, beginning on or after October 1, 2001.

We did not receive any comments on this proposal. Accordingly, we are adopting as final the proposed new § 412.312(e).

D. Restoration of the 2.1 Percent Reduction to the Standard Federal Capital Prospective Payment System Payment Rate

Section 1886(g)(1)(A) of the Act, as amended by section 4402 of Public Law 105–33, requires the Secretary to reduce the unadjusted standard Federal capital prospective payment system payment rate (and the unadjusted hospital-specific rate) by 2.1 percent for discharges on or after October 1, 1997, and through September 30, 2002, in addition to applying the budget neutrality factor used to determine the Federal capital prospective payment system payment rate in effect on September 30, 1995. The budget neutrality factor effective for September 30, 1995, was 0.8432 (59 FR 45416). Therefore, application of the budget neutrality factor (as specified under section 1886(g)(1)(A) of the Act) was equivalent to a 15.68 percent reduction to the unadjusted standard Federal capital prospective payment system payment rate and the unadjusted hospital-specific rate in effect on September 30, 1997. The additional 2.1 reduction to the rates in effect on September 30, 1997 resulted in a total reduction of 17.78 percent.

Accordingly, under the statute, the additional 2.1 percent reduction no longer applies to discharges occurring after September 30, 2002 (§ 412.308(b)(5)). Therefore, in the May 9, 2002 proposed rule (67 FR 31489), we proposed to revise § 412.308(b) to add a new paragraph (b)(6) to restore the 2.1 percent reduction to the unadjusted standard Federal capital prospective payment system payment rate (as provided under § 412.308(c)) for discharges occurring on or after October 1, 2002, to the level that it would have been without the reduction. (Since FY 2001 was the final year of the 10-year transition period, we no longer update the hospital-specific rate and, therefore, we also no longer restore the 2.1 percent reduction to that rate as provided under § 412.328(e)(1).)

As described in the August 29, 1997 final rule (62 FR 46012), we determined the reduction factor for FY 1998 by deducting both the FY 1995 budget neutrality factor (0.1568) and the 2.1 percent reduction (0.021) from 1 (1 − 0.1568 − 0.021 = 0.8222). We then applied the 0.8222 to the unadjusted standard Federal rate. Therefore, to determine the adjustment factor needed to restore the 2.1 percent reduction, we would divide the amount of the adjustment without the 2.1 percent reduction (1 − 0.1568 = 0.8432) by the amount of the adjustment with the 2.1 percent reduction (0.8222). Accordingly, we proposed to restore the 2.1 percent reduction for discharges occurring on or after October 1, 2002, under proposed § 412.308(b)(6), by applying a factor of 1.02554 (0.8432/0.8222) to the unadjusted standard Federal capital prospective payment system payment rate under § 412.308(c), that was in effect on September 30, 2002.

We did not receive any comments on this proposal and are, therefore, adopting as final the proposed new § 412.308(b)(6).

E. Clarification of Special Exceptions Policy

Under the special exceptions provisions at § 412.348(g), an additional payment may be made through the 10th year beyond the end of the capital prospective payment system transition period for eligible hospitals that meet (1) a project need requirement as described at § 412.348(g)(2), which, in the case of certain urban hospitals, includes an excess capacity test described at § 412.348(g)(4); and (2) a project size requirement as described at § 412.348(g)(5). In accordance with § 412.348(g)(7), hospitals are eligible to receive special exceptions payments for the 10 years after the cost reporting year in which they complete their project, which can be no later than the hospital's cost reporting period beginning before October 1, 2001.

During the 10-year capital prospective payment system transition period, regular exceptions under §§ 412.348(b) through (e) are paid the same as or more (between 70 percent and 90 percent of costs, depending on the type of hospital) than the special exceptions provision under § 412.348(g) (70 percent for all eligible hospitals). Therefore, it was not until cost reporting periods beginning on or after October 1, 2001 (the end of the transition period) that eligible hospitals could actually begin receiving additional payments under the special exceptions provision. As we stated in the July 30, 1999 final rule (64 FR 41528), we believe that, since any substantive changes to this policy could have a significant impact, the appropriate forum for addressing the special exceptions policy is through the legislative process in Congress rather than the regulations process. Since hospitals are beginning to receive additional payments under this provision, we have received several

questions regarding the current policy at § 412.348(g). Therefore, in the May 9, 2002 proposed rule (67 FR 31490), we did not propose any changes to the special exceptions policy. However, we did provide the following clarifications to the existing regulations.

Under § 412.348(g)(1), to be eligible for special exception payments, a hospital must be either a sole community hospital (SCH), an urban hospital with at least 100 beds that has a disproportionate share (DSH) percentage of at least 20.2 percent or qualify for DSH payments under § 412.106(c)(2), or a hospital with a combined Medicare and Medicaid inpatient utilization of at least 70 percent. Because a hospital's SCH status, DSH patient percentage, and combined utilization may fluctuate from one cost reporting year to the next, the special exceptions eligibility criteria are applied for each cost reporting period throughout the 10-year special exceptions period. A hospital receives special exceptions payments only for those years in the 10-year period in which it meets the eligibility requirements in § 412.348(g)(1). Therefore, a hospital might be eligible for a special exception payment in one year, not be eligible the next year, and then subsequently qualify during the 10-year special exceptions period.

The project need criteria in § 412.348(g)(2) also state that a hospital must obtain any required approval from a State or local planning authority. However, in States where a certificate of need or approval is not required by the State or local planning authority, the hospital must provide the fiscal intermediary with appropriate documentation (such as project plans from the hospital's board of directors) that demonstrates that the requirements of § 412.348(g)(3) concerning the age of assets test and § 412.348(g)(4) concerning the excess capacity test for urban hospitals are met. We understand that a State planning authority and a hospital may define a project differently. Accordingly, we will allow the hospital to use either the definition provided by the project within the certificate of need (in States where a certificate of need is required), or other appropriate documentation provided from the hospital's project plans (such as project plans as specified in the minutes of the meetings of the hospital's board of directors).

In determining a hospital's special exceptions payment amount, as described in § 412.348(g)(8), for each cost reporting period, the cumulative payments made to the hospital under the capital prospective payment system are compared to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the capital prospective payment system. This comparison is offset by any amount by which the hospital's current year Medicare inpatient operating and capital prospective payment system payments (excluding 75 percent of its operating DSH payments) exceed its Medicare inpatient operating and capital costs (or its Medicare inpatient margin). The minimum payment level is 70 percent for all hospitals, regardless of class, as set forth in § 412.348(g)(6), for the duration of the special exceptions provision.

In order to assist our fiscal intermediaries in determining the end of the 10-year period in which an eligible hospital will no longer be entitled to receive special exception payments, § 412.348(g)(9) requires that hospitals eligible for special exception payments submit documentation to the intermediary indicating the completion date of their project (the date the project was put in use for patient care) that meets the project need and project size requirements outlined in §§ 412.348(g)(2) through (g)(5). In order for an eligible hospital to receive special exception payments, this documentation had to be submitted in writing to the intermediary by the later of October 1, 2001, or within 3 months of the end of the hospital's last cost reporting period beginning before October 1, 2001, during which a qualifying project was completed.

We did not receive any comments on this clarification.

VII. Changes for Hospitals and Hospital Units Excluded From the Acute Care Hospital Inpatient Prospective Payment System

A. Payments to Excluded Hospitals and Hospital Units (§§ 413.40(c), (d), and (f))

1. Payments to Existing Excluded Hospitals and Hospital Units

Section 1886(b)(3)(H) of the Act (as amended by section 4414 of Public Law 105–33) established caps on the target amounts for certain existing hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system for cost reporting periods beginning on or after October 1, 1997 through September 30, 2002. For this period, the caps on the target amounts apply to the following three classes of excluded hospitals or units: psychiatric hospitals and units, rehabilitation hospitals and units, and long-term care hospitals.

In accordance with section 1886(b)(3)(H)(i) of the Act and effective for cost reporting periods beginning on or after October 1, 2002, payments to these classes of existing excluded hospitals or hospital units are no longer subject to caps on the target amounts. In accordance with existing §§ 413.40(c)(4)(ii) and (d)(1)(i) and (ii), where applicable, these excluded hospitals and hospital units continue to be paid on a reasonable cost basis, and payments are based on their Medicare inpatient operating costs, not to exceed the ceiling. The ceiling will be computed using the hospital's or unit's target amount from the previous cost reporting period updated by the rate-of-increase specified in § 413.40(c)(3)(viii) of the regulations and then multiplying this figure by the number of Medicare discharges. Effective for cost reporting periods beginning on or after October 1, 2002, rehabilitation hospitals and units are no longer paid on a reasonable cost basis but will be paid under the inpatient rehabilitation facility prospective payment system. Moreover, we have proposed the establishment of a DRG-based prospective payment system for long-term care hospitals (LTCHs) (67 FR 13415). As part of this process, we proposed a 5-year transition period from reasonable cost-based reimbursement to a fully Federal prospective payment system. However, a LTCH, subject to the blend methodology, may elect to be paid based on a 100 percent of the Federal prospective rate. (See sections VII.A.3. and 4. for a more detailed discussion.)

Comment: One commenter requested clarification as to whether payment to excluded hospitals and units are subject to the TEFRA bonus and penalty provisions and continuous improvement bonuses.

Response: Certain providers that are excluded from the acute care hospital inpatient prospective payment system will continue to receive bonus/relief payments as well as continuous improvement bonus payments, when appropriate, as provided for in § 413.40(d).

Comment: With regard to the expiration of the caps on target amounts for excluded hospitals and units, a commenter requested clarification as to how the FY 2003 target rate is to be determined.

Response: Our regulations at § 413.40(c)(4)(ii) state that ''the target amount equals the hospital's target amount for the previous cost reporting period, increased by the update factor for the subject cost reporting period * * *.'' Thus, for cost reporting periods beginning in FY 2003, the hospital or

unit should use its previous year's target amount, updated by the appropriate rate-of-increase percentage.

2. Updated Caps for New Excluded Hospitals and Units

Section 1886(b)(7) of the Act establishes a payment limitation for new psychiatric hospitals and units, new rehabilitation hospitals and units, and new long-term care hospitals. A discussion of how the payment limitation was calculated can be found in the August 29, 1997 final rule with comment period (62 FR 46019); the May 12, 1998 final rule (63 FR 26344); the July 31, 1998 final rule (63 FR 41000); and the July 30, 1999 final rule (64 FR 41529). Under the statute, a ''new'' hospital or unit is a hospital or unit that falls within one of the three classes of hospitals or units (psychiatric, rehabilitation or long-term care) that first receives payment as a hospital or unit excluded from the acute care hospital inpatient prospective payment system on or after October 1, 1997. The amount of payment for a ''new'' hospital or unit will be determined as follows:

- Under existing § 413.40(f)(2)(ii), for the first two 12-month cost reporting periods, the amount of payment is the lesser of: (1) The operating costs per case; or (2) 110 percent of the national median (as estimated by the Secretary) of the target amounts for the same class of hospital or unit for cost reporting periods ending during FY 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital or unit first receives payments under section 1886 of the Act, as adjusted for differences in area wage levels.
- Under existing § 413.40(c)(4)(iii)(B)(4)(v), for cost reporting periods following the hospital's or unit's first two 12-month cost reporting periods, the target amount is equal to the amount determined under section 1886(b)(7)(A)(i) of the Act for the third period, updated by the applicable hospital market basket increase percentage.

The amounts included in the following table reflect the updated 110 percent of the national median target amounts for each class of new excluded hospitals and hospital units for cost reporting periods beginning during FY 2003. These figures are updated with the most recent data available to reflect the market basket increase percentage of 3.5 percent. This percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient hospital services (as projected by CMS's Office of the Actuary based on its historical experience with the hospital inpatient prospective payment system). For a new provider, the labor-related share of the target amount is multiplied by the appropriate geographic area wage index, without regard to prospective payment system reclassifications, and added to the nonlabor-related share in order to determine the per case limit on payment under the statutory payment methodology for new providers.

Class of excluded hospital or unit	FY 2003 labor-related share	FY 2003 nonlabor-related share
Psychiatric	$ 7,054	$ 2,804
Long-Term Care	17,286	6,872

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation is no longer applicable to new rehabilitation hospitals and units since they will be paid under the inpatient rehabilitation facility prospective payment system.

3. Establishment of a Prospective Payment System for Inpatient Rehabilitation Hospitals and Units

Section 1886(j) of the Act, as added by section 4421(a) of Public Law 105–33, provided the phase-in of a case-mix adjusted prospective payment system for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation hospital unit (referred to in the statute as rehabilitation facilities) for cost reporting periods beginning on or after October 1, 2000 and before October 1, 2002, with a fully implemented prospective payment system for cost reporting periods beginning on or after October 1, 2002. Section 1886(j) of the Act was amended by section 125 of Public Law 106–113 to require the Secretary to use a discharge as the payment unit under the prospective payment system for inpatient hospital services furnished by rehabilitation facilities and to establish classes of patient discharges by functional-related groups. Section 305 of Public Law 106–554 further amended section 1886(j) of the Act to allow rehabilitation facilities, subject to the blend methodology, to elect to be paid the full Federal prospective payment rather than the transitional period payments specified in the Act.

On August 7, 2001, we issued a final rule in the **Federal Register** (66 FR 41316) establishing the prospective payment system for inpatient rehabilitation facilities, effective for cost reporting periods beginning on or after January 1, 2002. Under the inpatient rehabilitation prospective payment system, for cost reporting periods beginning on or after January 1, 2002, and before October 1, 2002, payment will consist of 33⅓ percent of the facility-specific payment amount (based on the reasonable cost-based reimbursement methodology) and 66⅔ percent of the adjusted Federal prospective payment. For cost reporting periods beginning on or after October 1, 2002, payment will be based entirely on the Federal prospective payment rate determined under the inpatient rehabilitation facility prospective payment system.

4. Implementation of a Prospective Payment System for Long-Term Care Hospitals

In accordance with the requirements of section 123 of Public Law 106–113, as modified by section 307(b) of Public Law 106–554, we proposed (as published in the March 22, 2002 proposed rule (67 FR 13415)) the establishment of a per discharge, DRG-based prospective payment system for long-term care hospitals as described in section 1886(d)(1)(B)(iv) of the Act for cost reporting periods beginning on or after October 1, 2002. As part of the implementation process, we proposed a 5-year transition period from reasonable cost-based reimbursement to the fully Federal prospective rate. We also proposed that certain long-term care hospitals may elect to be paid based on 100 percent of the Federal prospective rate. Under the March 22, 2002 proposed rule, a blend of the reasonable cost-based reimbursement percentage and the prospective payment Federal rate percentage would be used to determine a long-term care hospital's total payment under the prospective payment system during the transition period. We would expect long-term care hospitals to be paid under the full Federal prospective rate for cost reporting periods beginning on or after October 1, 2006. We are in the process of developing a final rule for the long-term care prospective payment system.

5. Changes in the Types of Patients Served or Inpatient Care Services That Distort the Comparability of the Cost Reporting Period to the Base Year are Grounds for Requesting an Adjustment Payment in Accordance with Section 1886(b)(4) of the Act

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment (exception) payments made to excluded hospitals and units, by reason of section 1886(b)(4) of the Act, during the previous fiscal year.

However, the data on adjustment payments made during the previous fiscal year are not available in time to publish a report describing the total amount of adjustment payments made to all excluded hospitals and units.

The process of requesting, adjudicating, and awarding an adjustment payment for a given cost reporting period is likely to occur over a 2-year period or longer. First, an excluded hospital or unit must file its cost report for a fiscal year with its intermediary within 5 months after the close of the fiscal year. The fiscal intermediary then reviews the cost report and issues a Notice of Program Reimbursement (NPR) in approximately 2 months after the filing of the cost report. If the hospital's operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment within 6 months from the date of the NPR. The intermediary, or CMS, depending on the type of adjustment requested, then reviews the request and determines if an adjustment payment is warranted. This determination is often not made until more than 6 months after the date the request is filed. Therefore, it is not possible to provide data in this final rule on adjustments granted for cost reports ending in the previous Federal fiscal year (that is, FY 2002), since those adjustments may not have been requested by the publication date of this final rule. However, in an attempt to provide interested parties with data on the most recent adjustments for which we do have data, we are publishing data on adjustments that were processed by the fiscal intermediaries or CMS during FY 2001.

The table below includes the most recent data available from the fiscal intermediaries and CMS on adjustment payments that were adjudicated during FY 2001. As indicated above, the adjustments made during FY 2001 only pertain to cost reporting periods ending in years prior to FY 2000. Total adjustment payments awarded to excluded hospitals and units during FY 2001 are $23,148,456. The table depicts for each class of hospital, in the aggregate, the number of adjustment requests adjudicated, the excess operating cost over the ceiling, and the amount of the adjustment payment.

Class of Hospital	Number	Excess cost over ceiling	Adjustment payment
Psychiatric	38	$23,211,026	$11,724,665
Rehabilitation	16	8,761,312	3,860,336
Long-Term Care	3	5,665,211	4,868,889
Children	3	2,696,518	1,043,565
Cancer	2	2,846,386	1,651,001

6. Technical Correction

On June 13, 2001, we published in the **Federal Register** an interim final rule (66 FR 32172) implementing section 307(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554). Section 307(a) provided for a 25-percent increase in TEFRA target amounts for long-term care hospitals ''For cost reporting periods beginning during FY 2001 * * *.'' When we addressed this provision in the interim final rule, we stated the effective date correctly in the preamble language. However, in the regulation text, we inadvertently used an incorrect effective date. We are making the conforming change to reflect the correct date in this final rule.

B. Criteria for Exclusion of Satellite Facilities From the Hospital Inpatient Prospective Payment System

Existing regulations at 42 CFR 412.22(e) define a hospital-within-a-hospital as a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Section 412.22(h), relating to satellites of hospitals excluded from the acute care hospital inpatient prospective payment system, defines a satellite facility as a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Section 412.25(e), relating to satellites of excluded hospital units, defines a satellite facility as a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Because of the similarities between the definitions of the two types of satellite facilities and the definition of a hospital-within-a-hospital, questions have been raised as to whether satellite facilities must meet the ''hospital-within-a-hospital'' criteria in § 412.22(e) regarding having a governing body, chief medical officer, medical staff, and chief executive officer that are separate from those of the hospital with which space is shared.

Although the separateness of satellite facilities of excluded hospitals and satellite facilities of excluded units of hospitals is not explicitly required under existing regulations, we believe these two types of satellite facilities are similar enough to hospitals-within-hospitals to warrant application of more closely related criteria to all of them. Specifically, satellite facilities are like hospitals-within-hospitals in that the satellites are physically located in acute care hospitals that are paid for their inpatient services under the acute care hospital inpatient prospective payment system. Moreover, both satellite facilities and hospitals-within-hospitals provide inpatient hospital care that is paid for at higher rates than would apply if the facility were treated by Medicare as a part of the acute care hospital.

In view of these facts, it is important that we establish clear criteria for ensuring that these facilities are not merely units of the acute care hospitals in which they are located, but are, in fact, organizationally and functionally separate from those hospitals. Therefore, in the May 9, 2002 proposed rule, we proposed to revise § 412.22(h)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2002, a hospital having a satellite facility would qualify for exclusion from the acute care hospital inpatient prospective payment system only if that satellite facility is: (1) Not under the authority or control of the governing body or chief executive officer of the hospital in which it is located; and (2) it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located. We also proposed to revise § 412.25(e)(2)(iii) to state that, effective for cost reporting periods beginning on or after October 1, 2002, a hospital unit having a satellite facility would qualify for exclusion from the acute care hospital inpatient prospective payment system only if the satellite facility is not under the

authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

Comment: One commenter stated that the use of the word ''authority'' in the criteria under § 412.25(e) of the proposed rule is ambiguous and unnecessary. The commenter expressed concern that the term could be construed in a manner that would undercut the ability of hospitals to provide necessary services. Therefore, the commenter believed that the word ''authority'' should be omitted from the final regulations. In addition, the commenter recommended that the most practical way to apply hospitalswithinhospitals criteria effectively to satellite facilities would be to amend § 412.22(e) to make it apply to both types of facilities or to incorporate those criteria by reference in proposed § 412.22(h)(2). The commenter believed that these revisions would be in keeping with CMS' intent and would result in a proper policy of treating hospitals-within-hospitals and satellite facilities equitably.

Response: After a review of the pertinent regulations, we agree with the commenter that the word ''authority'' should not be referenced in the regulations. We believe that deleting the reference allows for consistency between those criteria set forth for satellite facilities and those for hospitals-within-hospitals. Accordingly, in this final rule, we are revising §§ 412.22(h)(2)(iii)(A) and 412.25(e)(2)(iii)(A) to delete the word ''authority'' from the criteria.

However, we do not believe that revising § 412.22(e) to apply to both satellite facilities and hospitals-within-hospitals would be appropriate. A number of the criteria that apply to hospitals-within-hospitals would not be applicable to satellite facilities. One example is the requirement that the cost of services that the hospital-within-a-hospital receives from the ''host'' hospital is not more than 15 percent of the hospital's inpatient operating costs would not be an appropriate criterion. This criterion would not be appropriate for satellite facilities because the test would not only look at the costs incurred by the satellite facility but also at the costs incurred by the entire hospital, including both the satellite facility and the main hospital. For example, a main hospital has 100 beds and its satellite facility has 5 beds located in an acute care hospital. Since costs of the entire excluded hospital (at both the main hospital and the satellite facility) are reported on one cost report, by only looking at the costs that are shared between the satellite facility and the acute care hospital, the costs of services that the satellite facility receives from its ''host'' hospital will invariably be less than 15 percent of the costs of the entire hospital, even if all the costs of the satellite facility were incurred by the ''host'' hospital.

Comment: One commenter stated that given that long-term care hospitals and rehabilitation hospitals and units are now, or will be shortly, paid on prospective basis, the rule limiting the number of beds in a satellite facility may no longer be necessary. The commenter believed that the rules on hospitals-within-hospitals should be adequate to address CMS' concerns about payment advantage. Hence, the commenter recommended that the satellite facility rules be eliminated because they are no longer necessary and are burdensome.

Response: We have solicited comments regarding the bed limit for satellite facilities in the March 22, 2002 proposed rule to implement the long-term care hospital prospective payment system (67 FR 13464–13465). We will address the commenter's concerns along with any other comments received when we issue the final rule for the long-term care hospital prospective payment system.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 provides for a nationwide Medicare Rural Hospital Flexibility Program (MRHF). (MRHF replaced the 7-State Essential Access Community Hospital/Rural Primary Care Hospital (EACH/RPCH) program.) Under section 1820 of the Act, as amended, certain rural providers may be designated as critical access hospitals (CAHs) under the MRHF program if they meet qualifying criteria and the conditions for designation specified in the statute. Implementing regulations for section 1820 of the Act are located at 42 CFR Part 485, Subpart F.

2. Election of Optional Payment Method

Under existing regulations at 42 CFR 413.70(b), CAHs may elect to be paid for services to their outpatients under an optional method. Facilities making this election are paid an amount for each outpatient visit that is the sum of the reasonable costs of facility services, as determined under applicable regulations, and, for professional services otherwise payable to the physician or other practitioner, 115 percent of the amounts that otherwise would be paid for the services if the CAH had not elected payment under the optional method. To enable intermediaries to make these payments accurately and to avoid possible delays in or duplications of payment, we specify in § 413.70(b)(3) that each CAH electing payment under the optional method must inform the intermediary in writing of that election annually, at least 60 days before the start of the affected cost reporting period (65 FR 47100, August 1, 2000, and 66 FR 31272, June 13, 2001).

Since the publication of this regulation, some CAHs have expressed concern that requiring a 60-day advance notice of the election of the optional payment method limits their flexibility, and have suggested that a shorter advance notice period would be appropriate. We have contacted our fiscal intermediaries to obtain feedback on the feasibility of changing the period of advance notification, since the fiscal intermediaries would need to make appropriate bill processing changes to allow any shorter time for notification of election of the optional method. Some fiscal intermediaries stated that requiring less than 60 days' advance notice is impractical, while others believed that needed changes could be made with as little as 2 weeks' advance notice. Given the diversity of feedback on this issue and our desire to allow CAHs as much flexibility as possible, in the May 9 proposed rule, we proposed to revise § 412.30(b)(3) to allow the required advance notice period to be determined by each individual fiscal intermediary for the CAHs it services, as long as the required advance notice is not less than 14 days or more than 60 days before the start of each affected cost reporting period.

Comment: Several commenters recommended that the advanced notice period for CAHs to elect the all-inclusive billing option be set firmly at 30 days rather than allowing the fiscal intermediaries to choose a timeframe ranging from 15 days to 60 days. One commenter recommended retaining the 60-day notice to fiscal intermediaries. Another commenter stated that the implementation of such flexibility could pose problems and requested that intermediaries be required to communicate due dates effectively to CAHs. The commenters expressed concern that, by allowing each intermediary to set the period for advance notice confusion could arise, as well as result in different policies could be created across the country.

Response: We have reviewed the commenters' concerns with regard to our proposal to allow the fiscal intermediaries to set the timeframe for election of the optional payment method for CAHs. We agree that, by allowing this type of flexibility, there exists the possibility of confusion between the fiscal intermediaries and the CAHs. In addition, we recognize that various policies might be established across the country, instead of one national policy. Therefore, we believe that to help provide some stability and uniformity to this policy, it would be in the best interest of all concerned if a definite period of time is set for the CAHs to notify their intermediaries of their decision to elect the optional payment method. Accordingly, in light of the commenters concerns and input from the intermediaries, we believe that a sufficient amount of time for CAHs to notify their fiscal intermediaries of an election of the optional payment method is 30 days before the beginning of the affected cost reporting period. We believe this will give the fiscal intermediaries enough time so that payments can be made accurately, avoiding possible delays in, or duplication of, payment.

Accordingly, in this final rule, we are revising § 413.70(b)(3)(i) to state that the CAH's election of the optional payment method must be made to the fiscal intermediary 30 days prior to the start of the affected cost reporting period.

3. Use of the Resident Assessment Instrument (RAI) by CAHs

Among the existing regulations implementing section 1820 of the Act are specific conditions that a hospital must meet to be designated as a CAH. To help protect the health and safety of Medicare patients who are being furnished post-hospital skilled nursing facility (SNF) level of care in a CAH, our regulations require CAHs to comply with some, but not all, of the Medicare SNF conditions of participation at 42 CFR Part 483, Subpart B. Specifically, the regulations at § 485.645(d) provide that in order for a CAH to use its beds to provide post-hospital SNF care, the CAH must be in substantial compliance with nine of the SNF requirements contained in Part 483, Subpart B. Included among the nine requirements are requirements for comprehensive assessments, comprehensive care plans, and discharge planning as specified in § 483.20(b), (k), and (l). (We note that the existing § 485.645(d)(6) incorrectly cites these regulation cross-references as ''§ 483.20(b), (d), and (e).'' When we revised § 483.20 on December 23, 1997 (63 FR 53307), we inadvertently did not make conforming cross-reference changes in § 485.645(d)(6). In the May 9, 2002 proposed rule, we proposed to make these conforming cross-reference changes.) Section 483.20(b) provides that a facility must make a comprehensive assessment of a resident's needs using the resident assessment instrument (RAI), specified by the State, on all its swing-bed patients.

We have received inquiries regarding the need for CAHs to use the RAI for patient assessment and care planning. The inquirers consider the RAI a lengthy and burdensome instrument and pointed out that CMS currently does not require CAHs to report data from the RAI for quality or payment purposes.

We required former RPCHs to use the RAI for the assessment of swing-bed patients to avoid the possibility of negative outcomes that might extend the length of stays in these hospitals, which provided limited services. In addition, we believed that the use of the RAI would help to ensure that patient needs are met when patients are in the facility for an extended period of time. In addition, swing-bed hospitals were not required to use any patient assessment instrument because we believed that the hospital conditions of participation included requirements that were appropriate safeguards to protect the health and safety of Medicare patients. Currently, the regulations at § 483.20(f) require all long-term care facilities to collect and submit assessment data from the RAI to the State for quality and payment purposes. There are no such collection and submission requirements for CAHs.

We have gathered information from the provider community, State surveyors, and staff involved in the development of quality indicators and prospective payment system rates for SNFs to determine the feasibility of continuing to require CAHs to comply with the requirement for use of the RAI for patient assessments. Based on the information received, we can identify no specific patient benefits involved in requiring CAHs to use the RAI for patient assessment purposes.

In the interest of reducing burden, where possible, and based on our analysis of the current significance of the requirement for use of the RAI for patient assessments in CAHs, we proposed in the May 9, 2002 proposed rule to eliminate the requirement for CAHs to complete an RAI believing it to be appropriate and would not jeopardize patient health and safety. A CAH would still be required to capture assessment data for its SNF patients but would have the flexibility to document the assessment data in the medical record in a manner appropriate for its facility. We believe there are sufficient additional safeguards in the CAH regulations to ensure the health and safety of each SNF patient in a CAH. The facility would still be required to develop a comprehensive care plan for each SNF patient that includes measurable objectives and a timetable to meet a patient's medical, nursing, and psychosocial needs that are identified in an assessment. Also, a post-discharge plan of care would address post-hospital care needs of the patient. All of this information (assessment, plan of care, and discharge plans) must be maintained in the patient's medical record.

We proposed to revise § 485.645 to specify that CAHs are required to complete a comprehensive assessment, comprehensive care plan, and discharge plan in accordance with the requirements of § 483.20(b), (k), and (l), except that the CAH is not required to use the RAI specified by the State, and is not required to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b).

Comment: Fifteen commenters fully supported the elimination of the requirement that CAHs complete a lengthy patient assessment form for swing-bed patients, stating that the completion of the 400 plus question comprehensive assessment was an onerous and administrative burden, considering the RAI is not used for payment or quality purposes.

Response: We appreciate the commenters' support. As we stated in the proposed rule, we believe there are sufficient safeguards in the CAH regulations to ensure the health and safety of each swing-bed patient in a CAH. The facility would still be required to develop a comprehensive care plan for each swing-bed patient that includes measurable objectives and a timetable to meet a patient's medical, nursing, and psychosocial needs that are identified in an assessment.

Comment: One commenter disagreed with the elimination of the requirement. The commenter stated that CMS' failure to provide the basis for its decision to eliminate the RAI for CAHs violates the Administrative Procedure Act (APA). Further, the commenter stated that removing the RAI requirement would jeopardize quality of care for swing-bed patients in CAHs.

Response: In order to promulgate a substantive rule, the APA requires the agency to observe notice-and-comment rulemaking procedures, which we have

done. We believe that in the May 9, 2002 proposed rule, we clearly stated the issue and provided rationale for proposing the change.

Currently, all long-term care facilities are required to collect and submit assessment data to the State from the RAI for quality and payment purposes. There are no such collection and submission requirements for CAHs in the existing Medicare conditions of participation. On average, patients stay 10 days in a CAH swing bed. However, patients in SNFs have an average length of stay of approximately 25 days and patients in a nursing facility stay, on average, 230 days in a calendar year. The Medicare RAI assessment schedule for SNFs requires that the initial assessment be performed during days 1 through 5 of a patient's stay, but may be performed as late as days 6 through 8, termed ''grace days'', which gives staff additional flexibility in conducting the assessments. The initial assessment is used to assign patients to a resource utilization group (RUG), the case-mix group classification grouping that is used in establishing payments for the first 14 days of care. Subsequently, periodic assessments through the patient's stay at a SNF are performed to determine the RUG assignment and payment rate.

We believe that the commenter's concern that the removal of the RAI requirement for CAH's would jeopardize quality of care is unfounded. At this time, we believe that the quality of care interest in a CAH is better served by eliminating a requirement in which a very limited staff resource is required to complete a document with 400 plus questions for each swing-bed patient and from which data are not submitted to CMS, or compared with other facilities. Also, the existing requirement for a post-discharge plan of care would address post-hospital care needs of the patient.

We emphasize that the focus of the proposed rule was not to make major revisions to swing-bed requirements for CAHs. The proposal was to only eliminate the use of a specific form, the RAI tool. CAHs would still be required to complete comprehensive assessments on their swing-bed patients.

Comment: One commenter stated that quality of care measurements for swing-beds should be consistent and compatible to the measurement system used by nursing homes. The commenter suggested that a quality indicators program should be implemented in all facilities with swing beds.

Response: Quality measures currently are not calculated for CAHs because there are no data submitted to CMS to calculate. Further, even if data were available, the calculation of quality measures requires assessments to be conducted on days 5 and 14. The average length of stay in a CAH, which is 10 days, is inconsistent with this process.

CMS plans to develop an assessment tool in the future that will have a ''modular format'' whereby a provider with shorter patient stays would be able to collect a smaller set of data. In the future, we may consider whether or not it is appropriate and feasible to require CAHs to use and submit data from this specific format.

Comment: One commenter stated that there is no monitoring of compliance with conditions of participation in any swing beds. The commenter stated that surveys are infrequently conducted and when they are conducted, they are announced. The commenter also suggested that CMS apply the current long-term care transfer rule to all swing beds.

Response: We acknowledge that the monitoring and survey issues addressed by the commenters are important issues. However, the issues are outside the purview of this rule. The commenter's concerns will be shared with our survey and certification group.

VIII. MedPAC Recommendations

We have reviewed the March 1, 2002 report submitted by MedPAC to Congress and have given it careful consideration in conjunction with the policies set forth in this document. MedPAC's recommendations for payments for Medicare inpatient hospital services in its March 2002 report focused mainly on accounting for changes in input prices for the hospital market basket (Recommendation 2A) and on increases in the base rate for inpatient hospital services by applying the annual update factors (Recommendations 2B–1 and 2B–2).

In Recommendation 2A, MedPAC recommended that the Secretary should use wage and benefit proxies that most closely match the training and skill requirements of health care occupations in all input price indexes used for updating payments. MedPAC further indicated that, in determining index weights, measures specific to the health sector and to occupation categories in which health care plays a major role should be emphasized. Our decision to rebase and revise the hospital market basket, including cost category weights and price proxies, that is used in determining the update factors for payments for inpatient hospital services is presented in section IV of this final rule.

Recommendations 2B–1 and 2B–2 concerning the update factor for inpatient hospital operating costs and for hospitals and hospital distinct-part units excluded from the acute care hospital inpatient prospective payment system are discussed in Appendix B to this final rule.

IX. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are available in computer tape or cartridge format; however, some files are available on diskette as well as on the Internet at *http://www.hcfa.gov/stats/pufiles.htm.* In our May 9, 2002 proposed rule, we published a list of data files that are available for purchase (67 FR 31493 through 31495).

B. Information Collection Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The majority of the information collection requirements contained in this final rule are currently approved. Section IX.B.1. below lists the OMB approval numbers and the current expiration dates for the information collection requirements, referenced by specific Parts under Title 42 of the Code of Federal Regulations, in this final rule that are currently approved.

In the May 9, 2002 proposed rule, we solicited public comments on each of the information collection requirements referenced in the proposed rule that are described in section IX.B.2. of this final rule, as required under the PRA of 1995.

1. Currently Approved Requirements

Regulation references in 42 CFR	OMB approval number	Current expiration date
Part 412	0938–0691	September 30, 2002.
	0938–0050	May 31, 2004.
	0938–0573	September 30, 2002.
		October 31, 2003.
		September 30, 2002.
Part 413	0938–0050	May 31, 2004.
	0938–0667	October 31, 2002.
	0938–0477	July 31, 2005.

2. Requirements for Which Public Comment Were Sought in the May 9, 2002 Proposed Rule

Section 412.230 Criteria for an Individual Hospital Seeking Redesignation to Another Rural Area or an Urban Area

Appropriate Wage Data

As specified in § 412.230, a new hospital must accumulate and provide at least 1 year of wage data to CMS for the purposes of applying for reclassification. While this collection requirement is subject to the PRA, we believe that due to the fact that hospital's maintain this data for other business purposes or state reporting requirement, or both the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3) or both.

In addition, while this regulatory requirement is being added, the wage data collection requirement associated with this proposed regulatory requirement is currently approved under OMB collection 0938–0573 (Medicare Geographic Reclassification Review Criteria), with a current expiration date of September 30, 2002.

Section 413.65 Requirements for a determination that a facility or an organization had provider-based status

Responsibility for Obtaining Provider-Based Determinations

Under § 413.65, a potential main provider seeking an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider will be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. In addition, the provider seeking such an advance determination will be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

We estimate that the burden associated with these requirements is an average of 1.5 hours per provider, for approximately 3,000 providers per year, for an annual burden of 4,500 hours. This estimate is based on the fact that the providers currently maintain the necessary data and that minimal effort would be required to locate and review the appropriate data.

Clinical Services

The clinical services of the facility or organization seeking provider-based status and the main provider will be required to maintain an unified retrieval system (or cross reference) of the main provider for all patient medical records for those patients treated in the facility or organization.

While this collection requirement is subject to the PRA, we believe that due to the fact that hospitals maintain this data for other business purposes or state reporting requirements or both, the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3) or both.

We did not receive any public comments on the proposed information collection and recordkeeping requirements. The total burden associated with the new and revised requirements referenced in this section are 4,500 annual hours.

3. New Requirement in This Final Rule

Section 412.304(c)(2)(i)(A) Implementation of the Capital Prospective Payment System: Election by New Hospitals To Be Paid Based on 100 Percent of the Federal Rate

This section specifies that if a new hospital elects to be paid under the capital prospective payment system based on 100 percent of the Federal rate, instead of 85 percent of its allowable Medicare inpatient hospital capital-related costs, through its cost report ending at least 2 years after the hospital accepts its first patient, the new hospital must submit a written request to the fiscal intermediary. This request must be submitted by the later of December 1, 2002, or 60 days before the beginning of its cost reporting period.

We estimate that the burden associated with these requirements is an average of 1 hour per provider, for approximately 100 providers per year, for an annual burden of 100 hours.

The new information collection and recordkeeping requirements in this final rule will be submitted to the Office of Management and Budget (OMB) for review under the authority of the PRA. These requirements will not be effective until they have been approved by OMB.

If you have any comments on the information collection and recordkeeping requirements under § 412.304(c)(2)(i)(A), please mail the copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: John Burke, Attn.: CMS–1203–F, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Brenda Aguilar, CMS Desk Officer, Attn.: CMS–1203–F.

X. Waiver of Proposed Rulemaking

The Administrative Procedure Act generally requires that agency rules be published in the **Federal Register** as a notice of proposed rulemaking with a period for public comment (5 U.S.C. 533(b)). This notice-and-comment procedure can be waived, however, if an agency finds good cause that the procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

A. Technical Correction to Regulations Relating to DSH Adjustment Factor

On June 13, 2001, we Issued in the **Federal Register** an interim final with comment period (66 FR 32172) to

update the regulations to incorporate the changes made by section 211(b) of Public Law 106–554. Section 211(b) of Public Law 106–554 amended section 1886(d)(5)(F)(iv)(III) of the Act to revise the calculation of the DSH payment adjustment for hospitals affected by the revised thresholds as specified in section 211(a) of Public Law 106–554. These changes were effective for discharges on or after April 1, 2001, and no changes were made by section 211(b) for discharges prior to April 1, 2001. In the June 13, 2001 interim final rule with comment period, we inadvertently changed the adjustment factor for rural hospitals with fewer than 100 beds from 4 percent to 5 percent under § 412.106(d)(2)(iv)(A) for discharges occurring before April l, 2001. As indicated in section V.E.3 of this final rule, we are correcting this error

Since this change is being made to correct a technical error, we find that the notice-and-comment procedure is unnecessary, and, therefore, find good cause to waive the notice of proposed rulemaking and issue the correction as final.

B. Technical Correction to Regulations Relating to TEFRA Target Amount for Long-Term Care Hospitals

Also, in the June 13, 2001 interim final rule with comment period (66 FR 32172), we implemented section 307(a) of Public Law 106–554. Section 307(a) provided for a 25-percent increase in TEFRA target amounts for long-term care hospitals ''For cost reporting periods beginning during FY 2001 * * * .'' As indicated in section VII.A.6. of this preamble, in the June 2001 interim final rule with comment period, we stated the effective date correctly in the preamble language, but in the regulation text, we inadvertently used an incorrect effective date. We are making the conforming change to reflect the correct date in this final rule.

We find it unnecessary to undertake notice-and-comment rulemaking with regard to this change because our change merely conforms the regulation text to existing policy and provides technical correction to the regulations. It does not make any substantive changes to policy. Therefore, for good cause, we are waiving the notice-and-comment procedure with regard to this change.

C. Technical Corrections Relating to Affiliated Groups

As discussed in section V.I.3. of this preamble, we are making a technical change to the language under the definition of ''affiliated group'' under § 413.86(b) under paragraph (2) to reference the use of the more recent publications of the Graduate Medical Education Directory. Since this change updates a technical reference to an annual publication, we find the notice-and comment procedure is unnecessary, and therefore find good cause to waive the notice of proposed rulemaking and issue the correction as final.

When we issued the May 9, 2002 proposed rule, due to a typographical error, we inadvertently indicated that we proposed to make changes to § 413.86(g)(5)(iv) instead of § 413.86(g)(4)(iv) to incorporate revised provisions relating to determining the weighted number of FTE residents for hospitals that are part of the same affiliated group. As a result, we erroneously stated that we proposed to add a new paragraph under § 413.86(g)(5)(iv) and to redesignate paragraphs (g)(5)(iv), (g)(5)(v), and (g)(5)(vi) and paragraphs (g)(5)(v), (g)(5)(vi), and (g)(5)(vii), respectively, to accommodate the new paragraph. As discussed in section V.I.3. of this preamble, we are correcting these errors in this final rule. Since we are making these changes to correct a technical error, we find that the notice-and-comment procedure is unnecessary and therefore find good cause to waive the notice of proposed rulemaking and issue the correction in this final rule.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this final rule, 42 CFR Chapter IV is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:

1. The authority citation for Part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

2. Section 405.1885 is amended by revising paragraph (b), redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e), to read as follows:

§ 405.1885 Reopening a determination or decision.

* * * * *

(b)(1) An intermediary determination or an intermediary hearing decision must be reopened and revised by the intermediary if, within the 3-year period specified in paragraph (a) of this section, CMS—

(i) Provides notice to the intermediary that the intermediary determination or the intermediary hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or CMS general instructions in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the intermediary; and

(ii) Explicitly directs the intermediary to reopen and revise the intermediary determination or the intermediary hearing decision.

(2) A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

(3) Notwithstanding paragraph (b)(1)(i) of this section, CMS may direct the intermediary to reopen a particular intermediary determination or intermediary hearing decision in order to implement, for the same intermediary determination or intermediary decision—

(i) A final agency decision under §§ 405.1833, 405.1871(b), 405.1875, or 405.1877(a) of this part;

(ii) A final nonappealable court judgment; or

(iii) An agreement to settle an administrative appeal or a lawsuit.

* * * * *

(e) Notwithstanding an intermediary's discretion to reopen or not reopen an intermediary determination or an intermediary hearing decision under paragraphs (a) and (c) of this section, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an

intermediary hearing decision in accordance with paragraphs (a) and (c) of this section.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

B. Part 412 is amended as follows:

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 412.4 [Amended]

2. In § 412.4(f)(1),the reference ''paragraph (b) or (c)'' is removed and ''paragraph (b)(1) or (c)'' is added in its place.

3. Section 412.22 is amended by—

a. Revising the introductory text of paragraph (h)(2).

b. Republishing the introductory text of paragraph (h)(2)(iii).

c. Redesignating paragraphs (h)(2)(iii)(A) through (F) as paragraphs (h)(2)(iii)(B) through (G), respectively.

d. Adding new paragraph (h)(2)(iii)(A).

The revision, republication, and addition read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(h) Satellite facilities. * * *

(2) Except as provided in paragraph (h)(3) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

* * * * *

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

4. Section 412.25 is amended by—

a. Revising the introductory text of paragraph (e)(2).

b. Republishing the introductory text of paragraph (e)(2)(iii).

c. Redesignating paragraphs (e)(2)(iii)(A) through (F) as paragraphs (e)(2)(iii)(B) through (G), respectively.

d. Adding new paragraph (e)(2)(iii)(A).

The revision, republication, and addition read as follows:

§ 412.25 Excluded hospitals units: Common requirements.

* * * * *

(e) *Satellite facilities.* * * *

(2) Except as provided in paragraph (e)(3) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

* * * * *

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

§ 412.63 [Amended]

5. Section 412.63 is amended by—

a. In paragraph (x)(2)(i)(A), removing the phrase ''tabulating the hospital's data'' and adding in its place ''tabulating its data''.

b. Removing paragraphs (x)(3) and (x)(4).

c. Redesignating paragraph (x)(5) as paragraph (x)(3).

6. Section 412.80 is amended by revising paragraph (a)(2) to read as follows:

§ 412.80 Outlier cases: General provisions.

(a) *Basic rule.* * * *

(2) *Discharges occurring on or after October 1, 1997 and before October 1, 2001.* For discharges occurring on or after October 1, 1997 and before October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, as described in § 412.84(h), exceed the DRG payment for the case, payments for indirect costs of graduate medical education (§ 412.105), and payments for serving disproportionate share of low-income patients (§ 412.106), plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

* * * * *

7. Section 412.88 is amended by republishing the introductory text of paragraph (a) and revising paragraph (a)(1) to read as follows:

§ 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

(i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);

(ii) The payment determined under § 412.4(f) for transfer cases;

(iii) The payment determined under § 412.92(d) for sole community hospitals; or

(iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

* * * * *

8. Section 412.92 is amended by revising paragraph (c)(2), to read as follows: § 412.92

Special treatment: Sole community hospitals.

* * * * *

(c) *Terminology.* * * *

(2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

* * * * *

9. Section 412.105 is amended by—

A. Republishing the introductory text of paragraph (a).

B. Revising paragraph (a)(1).

C. Revising paragraph (f)(1)(iii)(A).

D. Revising paragraph (f)(1)(vi).

E. Amending the following cross-references in paragraph (f)(1):

i. In paragraph (f)(1)(vii), the reference ''§ 413.86(g)(12)'' is removed and ''§ 413.86(g)(13)'' is added in its place.

ii. In paragraph (f)(1)(viii), the reference ''§ 413.86 (g)(7)'' is removed and ''§ 413.86(g)(8)'' is added in its place.

iii. In paragraph (f)(1)(ix), the reference ''§ 413.86(g)(8)(i) and (g)(8)(ii) of the subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(ii) of the subchapter'' is added in its place; the reference ''§ 413.86(g)(8)(i) and (g)(8)(iii)(B) of this subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(iii)(B) of this subchapter'' is added in its place; and the reference ''§ 413.86(g)(8)(i) and (g)(8)(iii)(A) of the subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(iii)(A)'' is added it its place.

iv. In paragraph (f)(1)(x), the reference ''§ 413.86(g)(12)'' is removed and ''§ 413.86(g)(13)'' is added in its place; and the reference ''§ 413.86(g)(11)'' is removed and ''§ 413.86(g)(12)'' is added in its place.

v. In paragraph (f)(1)(xi), the reference ''§ 413.86(g)(9)'' is removed and ''§ 413.86(g)(10)'' is added in its place.

vi. In paragraph (f)(1)(xii), the reference ''§ 413.86(g)(10)'' is removed and ''§ 413.86(g)(11)'' is added in its place.

The revisions read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent residents (except as limited under paragraph (f) of this section) to the number of beds (as determined under paragraph (b) of this section).

(i) Except for the special circumstances for affiliated groups and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

(ii) The exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.

(iii) The exception for closed hospitals and closed programs described in paragraph (f)(1)(ix) of this section applies only through the end of the first 12-month cost reporting period in which the receiving hospital trains the displaced full-time equivalent residents.

(iv) In the cost reporting period following the last year the receiving hospital's full-time equivalent cap is adjusted for the displaced resident(s), the resident-to-bed ratio cap in paragraph (a)(1) of this section is calculated as if the displaced full-time equivalent residents had not trained at the receiving hospital in the prior year.

* * * * *

(f) *Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.* (1) * * *

(iii)(A) Full-time equivalent status is based on the total time necessary to fill a residency slot. No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of time worked in any areas of the hospital listed in paragraph (f)(1)(ii) of this section to the total time worked by the resident. A hospital cannot claim the time spent by residents training at another hospital. A part-time resident or one working in an area of the hospital other than those listed under paragraph (f)(1)(ii) of this section (such as a freestanding family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (f)(1)(ii) of this section, compared to the total time necessary to fill a full-time residency slot.

* * * * *

(vi) Hospitals that are part of the same affiliated group (as defined in § 413.86(b) of this subchapter) may elect to apply the limit at paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in § 413.86(g)(7) of this chapter.

* * * * *

§ 412.106 [Amended]

10. In § 412.106(d)(2)(iv)(A), the phrase ''5 percent'' is removed and the phase ''4 percent'' is added in its place.

* * * * *

11. Section 412.108 is amended by revising paragraph (b) to read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

* * * * *

(b) *Classification procedures.* (1) The fiscal intermediary determines whether a hospital meets the criteria specified in paragraph (a) of this section.

(2) A hospital must submit a written request along with qualifying documentation to its fiscal intermediary to be considered for MDH status based on the criterion under paragraph (a)(1)(iii)(C) of this section.

(3) The fiscal intermediary will make its determination and notify the hospital within 90 days from the date that it receives the hospital's request and all of the required documentation.

(4) A determination of MDH status made by the fiscal intermediary is effective 30 days after the date the fiscal intermediary provides written notification to the hospital. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

(5) The fiscal intermediary will evaluate on an ongoing basis, whether or not a hospital continues to qualify for MDH status. This evaluation includes an ongoing review to ensure that the hospital continues to meet all of the criteria specified in paragraph (a) of this section.

(6) If the fiscal intermediary determines that a hospital no longer qualifies for MDH status, the change in status will become effective 30 days after the date the fiscal intermediary provides written notification to the hospital.

(7) A hospital may reapply for MDH status following its disqualification only after it has completed another cost reporting period that has been audited and settled. The hospital must reapply for MDH status in writing to its fiscal intermediary and submit the required documentation.

(8) If a hospital disagrees with an intermediary's determination regarding the hospital's initial or ongoing MDH status, the hospital may notify its fiscal intermediary and submit other documentable evidence to support its claim that it meets the MDH qualifying criteria.

(9) The fiscal intermediary's initial and ongoing determination is subject to review under subpart R of Part 405 of this chapter. The time required by the fiscal intermediary to review the request is considered good cause for granting an extension of the time limit for the hospital to apply for that review.

* * * * *

12. Section 412.113 is amended by revising paragraphs (c)(2)(i)(D), (c)(2)(ii), and (c)(2)(iii) to read as follows:

§ 412.113 Other payments.

* * * * *

(c) *Anesthesia services furnished by hospital employed nonphysician anesthetists or obtained under arrangements.*

* * * * *

(2)(i) * * *

(D) Each qualified nonphysician anesthetist employed by or under contract with the hospital or CAH has agreed in writing not to bill on a reasonable charge basis for his or her patient care to Medicare beneficiaries in that hospital or CAH.

(ii) To maintain its eligibility for reasonable cost payment under paragraph (c)(2)(i) of this section in calendar years after 1989, a qualified hospital or CAH must demonstrate prior to January 1 of each respective year that for the prior year its volume of surgical procedures requiring anesthesia service did not exceed 500 procedures; or, effective October 1, 2002, did not exceed 800 procedures.

(iii) A hospital or CAH that did not qualify for reasonable cost payment for nonphysician anesthetist services furnished in calendar year 1989 can qualify in subsequent years if it meets the criteria in paragraphs (c)(2)(i)(A), (B), and (D) of this section, and demonstrates to its intermediary prior to the start of the calendar year that it met these criteria. The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987 and the year immediately preceding its election of reasonable cost payment, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 500 procedures, or, effective October 1, 2002, did not exceed 800 procedures.

* * * * *

13. Section 412.230 is amended by adding a new paragraph (e)(2)(iii) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(e) *Use of urban or other rural area's wage index.* * * *

(2) *Appropriate wage data.* * * *

(iii) For purposes of this paragraph (e)(2), if a new owner does not accept assignment of the existing hospital's provider agreement in accordance with § 489.18 of this chapter, the hospital will be treated as a new provider with a new provider number. In this case, the wage data associated with the previous hospital's provider number cannot be used in calculating the new hospital's 3-year average hourly wage. Once a new hospital has accumulated at least 1 year of wage data, it is eligible to apply for reclassification on the basis of those data.

* * * * *

14. Section 412.273 is amended by—

A. Revising the section heading.

B. Revising paragraphs (b)(2)(i) and (b)(2)(ii).

C. Adding a new paragraph (b)(2)(iii).

D. Redesignating paragraph (d) as paragraph (e).

E. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

* * * * *

(b) *Request for termination of approved 3-year wage index reclassifications.* * * *

(2) *Reapplication within the approved 3-year period.*

(i) If a hospital elects to withdraw its wage index application after the MGCRB has issued its decision, it may cancel its withdrawal in a subsequent year and request the MGCRB to reinstate its wage index reclassification for the remaining fiscal year(s) of the 3-year period.

(ii) A hospital may apply for reclassification for purposes of the wage index to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, regardless of whether the withdrawal or termination request is made within 3 years from the date of the withdrawal or termination.

(iii) In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1.

* * * * *

(d) *Process for canceling a previous withdrawal or termination.* A hospital may cancel a previous withdrawal or termination by submitting written notice of its intent to the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

* * * * *

15. Section 412.304 is amended by revising paragraph (c) to read as follows:

§ 412.304 Implementation of the capital prospective payment system.

* * * * *

(c) *Cost reporting periods beginning on or after October 1, 2001.*— (1) *General.* Except as provided in paragraph (c)(2) of this section, for cost reporting periods beginning on or after October 1, 2001, the capital payment amount is based solely on the Federal rate determined under §§ 412.308(a) and (b) and updated under § 412.308(c).

(2) *Payment to new hospitals.* For cost reporting periods beginning on or after October 1, 2002—

(i) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost report ending at least 2 years after the hospital accepts its first patient, unless the new hospital elects to be paid under the capital prospective payment system based on 100 percent of the Federal rate.

(A) If the new hospital elects to be paid based on 100 percent of the Federal rate, the new hospital must submit a written request to the fiscal intermediary by the later of December 1, 2002 or 60 days before the beginning of its cost reporting period.

(B) Once a new hospital elects to be paid based on 100 percent of the Federal rate, it may not revert to payment at 85 percent of its allowable Medicare inpatient hospital capital-related costs.

(ii) For the third year and subsequent years, the hospital is paid based on the Federal rate as described under § 412.312.

* * * * *

16. Section 412.308 is amending by adding a new paragraph (b)(6) to read as follows:

§ 412.308 Determining and updating the Federal rate.

* * * * *

(b) *Standard Federal rate.* * * *

(6) For discharges occurring on or after October 1, 2002, the 2.1 percent reduction provided for under paragraph (b)(5) of this section is eliminated from the unadjusted standard Federal rate in effect on September 30, 2002, used to determine the Federal rate each year under paragraph (c) of this section.

* * * * *

17. Section 412.312 is amended by adding a new paragraph (e) to read as follows:

§ 412.312 Payment based on the Federal rate.

* * * * *

(e) *Payment for extraordinary circumstances.* Payment for extraordinary circumstances is made as provided for in § 412.348(f) for cost reporting periods beginning on or after October 1, 2001.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

C. Part 413 is amended as follows:

1. The authority citation for Part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

2. Section 413.40 is amended by revising paragraph (c)(4)(iii)(A)(*2*) to read as follows:

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

* * * * *

(c) * * *

(4) * * *

(iii) * * *

(A) * * *

(*2*) In the case of long-term care hospitals, for cost reporting periods beginning on or after October 1, 2000, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors multiplied by 1.25.

* * * * *

3. Section 413.65 is amended by—

A. Revising paragraphs (a)(1)(ii), (a)(1)(ii)(G), and (a)(1)(ii)(H).

B. Adding new paragraphs (a)(1)(ii)(J) and (a)(1)(ii)(K).

C. Revising the definition of ''Department of a provider'', ''Provider-based entity'', and ''Remote location of a hospital'' under paragraph (a)(2).

D. Revising paragraphs (b)(2), (b)(3), (c) and (d).

E. Removing paragraph (j).

F. Redesignating paragraphs (h) and (i) as paragraphs (i) and (j), respectively.

G. Redesignating paragraph (f) as paragraph (h).

H. Redesignating paragraph (e) as paragraph (f).

I. Adding a new paragraph (e).

J. Revising redesignated paragraph (f).

K. Revising the introductory text of paragraph (g) and paragraphs (g)(1), (g)(2), and (g)(7).

L. Revising redesignated paragraphs (h), (i), and (j).

M. Revising paragraph (k).

N. Redesignating paragraphs (l), (m), and (n) as paragraphs (m), (n), and (o), respectively.

O. Adding a new paragraph (l).

P. Revising the heading of redesignated paragraph (n).

Q. Revising redesignated paragraph (o).

The revisions and addition read as follows:

§ 413.65 Requirements for a determination that a facility or an organization had provider-based status.

(a) *Scope and definitions.*—(1) *Scope.* * * *

(ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:

* * * * *

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services.

(H) Facilities, other than those operating as parts of CAHs, furnishing only physical, occupational, or speech therapy to ambulatory patients, for as long as the $1,500 annual cap on coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation.

* * * * *

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(K) Ambulances.

(2) *Definitions.* * * *

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term ''department of a provider'' does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

* * * * *

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

* * * * *

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ''remote location of a hospital'' does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.

(b) *Procedure for obtaining provider-based determinations.* * * *

(2) If a facility was treated as provider-based in relation to a hospital

or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated as a joint venture or under a management contract, the requirements of paragraph (f) or paragraph (h) of this section, as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

* * * * *

(c) *Reporting of material changes in relationships.* A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the provider.

(ii) The main provider and the facility or organization seeking status as a department of the provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location.* The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider, except when the requirements in paragraph (e)(3)(i), (e)(3)(ii), or (e)(3)(iii) of this section are met:

(i) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(e)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(ii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or

(C) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(ii)(A) or paragraph (e)(3)(ii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(ii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(ii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(iv) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(v) An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criteria in paragraphs (e)(3)(i) through (e)(3)(iii) of this section.

(f) *Provider-based status for joint ventures.* In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must—

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.*

(1) Hospital outpatient departments located either on or off the campus of the hospital that is the main provider must comply with the antidumping rules in §§ 489.20 (l), (m), (q), and (r) and § 489.24 of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.

* * * * *

(7) When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, and the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, the hospital must provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability).

(i) The notice must be one that the beneficiary can read and understand.

(ii) If the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.

(iii) The hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

(iv) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(v) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of § 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

* * * * *

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of ''leased'' employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) *Inappropriate treatment of a facility or organization as provider-based.—(1) Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will—

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

(2) *Exception for good faith effort.* CMS will not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if, during all of that period—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) *Notice to provider.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners—

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

(k) *Temporary treatment as provider-based.* If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(l) *Correction of errors.* (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) *Status of Indian Health Service and Tribal facilities and organizations.* * * * * * *

(n) *FQHCs and ''look alikes.''* * * *

(o) *Effective date of provider-based status.*—(1) *General rule.* Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) *Inappropriate treatment as provider-based or not reporting material change.* Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part.

4. Section 413.70 is amended by revising paragraph (b)(3)(i) to read as follows:

§ 413.70 Payment for services of a CAH.

* * * * * *

(b) *Payment for outpatient services furnished by CAH.* * * *

(3) *Election to be paid reasonable costs for facility services plus fee schedule for professional services.* (i) A CAH may elect to be paid for outpatient services in any cost reporting period under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section. This election must be made in writing, made on an annual basis, and delivered to the fiscal intermediary servicing the CAH at least 30 days before the start of each affected cost reporting period. An election of this

payment method, once made for a cost reporting period, remains in effect for all of that period and applies to all services furnished to outpatients during that period.

* * * * *

5. Section 413.86 is amended by—

A. Revising the definition of ''Affiliated group'' under paragraph (b).

B. Adding definitions of ''Affiliation agreement'' and ''Shared rotational arrangement'' in alphabetical order under paragraph (b).

C. Revising the last sentence of paragraph (e)(5)(i), introductory text.

D. Revising paragraph (e)(5)(i)(B).

E. Adding a new paragraph (e)(5)(i)(C).

F. Revising paragraph (f)(2).

G. Republishing the introductory text of paragraph (g)(4) and revising paragraph (g)(4)(iv).

H. Redesignating paragraphs (g)(7) through (g)(12) as paragraphs (g)(8) through (g)(13), respectively.

I. Adding a new paragraph (g)(7).

J. Amending the following cross-references:

i. In paragraph (g)(5)(vi), ''paragraph (g)(8)'' is removed and ''paragraph (g)(9)'' is added in its place.

ii. In paragraph (g)(6), ''paragraph (g)(12)'' is removed and ''paragraph (g)(13)'' is added in its place.

iii. In redesignated paragraphs (g)(8)(iv) and (g)(8)(v), ''paragraph (g)(7)'' is removed and ''paragraph (g)(8)'' is added in its place.

iv. In redesignated paragraph (g)(9)(i), ''paragraph (g)(8)'' is removed and ''paragraph (g)(9)'' is added in its place.

v. In the introductory text of redesignated paragraph (g)(9)(iii), ''paragraph (g)(8)(iii)(B)'' is removed and ''paragraph (g)(9)(iii)(B)'' is added in its place; and ''paragraph (g)(8)(iii)(A)'' is removed and ''paragraph (g)(9)(iii)(A)'' is added in its place.

vi. In redesignated paragraph (g)(9)(iii)(A)(*2*), ''paragraph (g)(8)(iii)(B)(*2*)'' is removed and ''paragraph (g)(9)(iii)(B)(*2*)'' is added in its place.

vii. In the introductory text of redesignated paragraph (g)(12), ''paragraph (g)(11)(i) through (g)(11)(vi)'' is removed and ''paragraph (g)(12)(i) through (g)(12)(vi)'' is added in its place.

The additions and revisions read as follows:

§ 413.86 Direct graduate medical education payments.

* * * * *

(b) *Definitions.* * * *

Affiliated group means—

(1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in § 412.62(f) of this subchapter) or in contiguous area and meet the rotation requirement in paragraph (g)(7)(ii) of this section.

(2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in paragraph (g)(7)(ii) of this section, and are jointly listed—

(i) As the sponsor, primary clinical site or major participating institution for one or more programs as these terms are used in the most current publication of the *Graduate Medical Education Directory;* or

(ii) As the sponsor or is listed under ''affiliations and outside rotations'' for one or more programs in operation in *Opportunities, Directory of Osteopathic Postdoctoral Education Programs.*

(3) Two or more hospitals that are under common ownership and, effective for all affiliation agreements beginning July 1, 2003, meet the rotation requirement in paragraph (g)(7)(ii) of this section.

Affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in an affiliated group, as defined in this section, that specifies—

(1) The term of the agreement (which, at a minimum is one year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect GME FTE caps in effect prior to the affiliation;

(3) The total adjustment to each hospital's FTE caps in each year that the affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;

(4) The adjustment to each participating hospitals' FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the affiliated group for each year the affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with paragraph (3) of this definition); and

(5) The names of the participating hospitals and their Medicare provider numbers.

* * * * *

Shared rotational arrangement means a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

(e) *Determining per resident amounts for the base period.*

(5) Exceptions—(i) *Base period for certain hospitals.* * * * The per resident amount is based on the lower of the amount specified in paragraph (e)(5)(i)(A) or in paragraph (e)(5)(i)(B) of this section, subject to the provisions of paragraph (e)(5)(i)(C) of this section.

(B) Except as specified in paragraph (e)(5)(i)(C) of this section—

(*1*) For base periods that begin before October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under part 412 of this chapter.

(*2*) For base periods beginning on or after October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(C) If, under paragraph (e)(5)(i)(B)(*1*) or (e)(5)(i)(B)(*2*) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in § 412.62(f)(1)(i) of this chapter.

* * * * *

(f) *Determining the weighted number of FTE residents.* * * *

(2) No individual may be counted as more than one FTE. A hospital cannot claim the time spent by residents training at another hospital. Except as provided in paragraphs (f)(3) and (f)(4) of this section, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

* * * * *

(g) *Determining the weighted number of FTE residents.* * * *

(4) For purposes of determining direct graduate medical education payment—

* * * * *

(iv) Hospitals that are part of the same affiliated group (as described under paragraph (b) of this section) may elect to apply the limit on an aggregate basis as described under paragraph (g)(7) of this section.

* * * * *

(7) A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (g)(5)(iii) of this section, to reflect residents added or subtracted because the hospital is participating in an affiliated group (as defined under paragraph (b) of this section). Under this provision—

(i) Each hospital in the affiliated group must submit the affiliation agreement, as defined under paragraph (b) of this section, to the CMS fiscal intermediary servicing the hospital and send a copy to CMS's Central Office no later than July 1 of the residency program year during which the affiliation agreement will be in effect.

(ii) Each hospital in the affiliated group must have a shared rotational arrangement, as defined in paragraph (b) of this section, with at least one other hospital within the affiliated group, and all of the hospitals within the affiliated group must be connected by a series of such shared rotational arrangements.

(iii) During the shared rotational arrangements under an affiliation agreement, as defined in paragraph (b) of this section, more than one of the hospitals in the affiliated group must count the proportionate amount of the time spent by the resident(s) in its FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(iv) The net effect of the adjustments (positive or negative) on the affiliated hospitals' aggregate FTE cap for each affiliation agreement must not exceed zero.

(v) If the affiliation agreement terminates for any reason, the FTE cap of each hospital in the affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (g)(4) of this section.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

D. Part 485 is amended as follows:

1. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1396hh).

2. In § 485.645, the introductory text of paragraph (d) is republished and paragraph (d)(6) is revised, to read as follows.

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'').

* * * * *

(d) *SNF services.* The CAH is substantially in compliance with following SNF requirements contained in Subpart B of Part 483 of this chapter.

* * * * *

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare— Hospital Insurance)

Dated: July 24, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 24, 2002.

Tommy G. Thompson,

Secretary.

[**Editorial Note:** The following Addendum and appendixes will not appear in the Code of Federal Regulations.]

Addendum—Schedule of Standardized Amounts Effective With Discharges Occurring On or After October 1, 2002 and Update Factors and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2002

I. Summary and Background

In this Addendum, we are setting forth the amounts and factors for determining prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs. We are also setting forth rate-of-increase percentages for updating the target amounts for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system.

For discharges occurring on or after October 1, 2002, except for SCHs, MDHs, and hospitals located in Puerto Rico, each hospital's payment per discharge under the acute care hospital inpatient prospective payment system will be based on 100 percent of the Federal national rate.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or 75 percent of the updated hospital-specific rate based on FY 1996 costs per discharge, plus the greater of 25 percent of the updated FY 1982 or FY 1987 hospital-specific rate or 50 percent of the Federal DRG payment rate. Section 213 of Public Law 106–554 amended section 1886(b)(3) of the Act to allow all SCHs to rebase their hospital-specific rate based on their FY 1996 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever is higher. MDHs do not have the option to use their FY 1996 hospital-specific rate.

For hospitals in Puerto Rico, the payment per discharge is based on the sum of 50 percent of a Puerto Rico rate and 50 percent of a Federal national rate. (See section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for FY 2003. The changes, to be applied prospectively effective with discharges occurring on or after October 1, 2002, affect the calculation of the Federal rates. In section III. of this Addendum, we discuss our changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2003. Section IV. of this Addendum sets forth our changes for determining the rate-of-increase limits for hospitals excluded from the prospective payment system for FY 2003. The tables to which we refer in the preamble to this final rule are presented in section V. of this Addendum.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for FY 2003

The basic methodology for determining prospective payment rates for hospital inpatient operating costs is set forth at § 412.63. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico is set forth at §§ 412.210 and 412.212. Below, we discuss the factors used for determining the prospective payment rates.

In summary, the standardized amounts set forth in Tables 1A and 1C of section V. of this Addendum reflect—

- Updates of 2.95 percent for all areas (that is, the market basket percentage increase of 3.5 percent minus 0.55 percentage points);
- An adjustment to ensure the DRG recalibration and wage index update and changes are budget neutral, as provided for under sections 1886(d)(4)(C)(iii) and (d)(3)(E) of the Act, by applying new budget neutrality adjustment factors to the large urban and other standardized amounts;
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for in section 1886(d)(8)(D) of the Act, by removing the FY

2002 budget neutrality factor and applying a revised factor;

- An adjustment to apply the new outlier offset by removing the FY 2002 outlier offsets and applying a new offset; and
- An adjustment in the Puerto Rico standardized amounts to reflect the application of a Puerto Rico-specific wage index.

A. Calculation of Adjusted Standardized Amounts

1. Standardization of Base-Year Costs or Target Amounts

Section 1886(d)(2)(A) of the Act required the establishment of base-year cost data containing allowable operating costs per discharge of inpatient hospital services for each hospital. The preamble to the September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data were established in the initial development of standardized amounts for the acute care hospital inpatient prospective payment system.

Section 1886(d)(9)(B)(i) of the Act required us to determine the Medicare target amounts for each hospital located in Puerto Rico for its cost reporting period beginning in FY 1987. The September 1, 1987 final rule (52 FR 33043, 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

The standardized amounts are based on per discharge averages of adjusted hospital costs from a base period or, for Puerto Rico, adjusted target amounts from a base period, updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. Sections 1886(d)(2)(B) and (d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, indirect medical education costs, and costs to hospitals serving a disproportionate share of low-income patients.

Under sections 1886(d)(2)(H) and (d)(3)(E) of the Act, in making payments under the acute care hospital inpatient prospective payment system, the Secretary estimates from time to time the proportion of costs that are wages and wage-related costs. Since October 1, 1997, when the market basket was last revised, we have considered 71.1 percent of costs to be labor-related for purposes of the acute care hospital inpatient prospective payment system. As discussed in section IV. of the preamble to this final rule, we are not revising the labor share of the standardized amount (the proportion adjusted by the wage index). The average labor share in Puerto Rico is 71.3 percent. We are revising the discharge-weighted national standardized amount for Puerto Rico to reflect the proportion of discharges in large urban and other areas from the FY 2001 MedPAR file.

2. Computing Large Urban and Other Area Average Standardized Amounts

Sections 1886(d)(2)(D) and (d)(3) of the Act require the Secretary to compute two average standardized amounts for discharges occurring in a fiscal year: one for hospitals located in large urban areas and one for hospitals located in other areas. In addition, under sections 1886(d)(9)(B)(iii) and (d)(9)(C)(i) of the Act, the average standardized amount per discharge must be determined for hospitals located in large urban and other areas in Puerto Rico. In accordance with section 1886(b)(3)(B)(i) of the Act, the large urban average standardized amount is 1.6 percent higher than the other area average standardized amount.

Section 1886(d)(2)(D) of the Act defines ''urban area'' as those areas within a Metropolitan Statistical Area (MSA). A ''large urban area'' is defined as an urban area with a population of more than 1 million. In addition, section 4009(i) of Public Law 100–203 provides that a New England County Metropolitan Area (NECMA) with a population of more than 970,000 is classified as a large urban area. As required by section 1886(d)(2)(D) of the Act, population size is determined by the Secretary based on the latest population data published by the Bureau of the Census. Urban areas that do not meet the definition of a ''large urban area'' are referred to as ''other urban areas.'' Areas that are not included in MSAs are considered ''rural areas'' under section 1886(d)(2)(D) of the Act. Payment for discharges from hospitals located in large urban areas will be based on the large urban standardized amount. Payment for discharges from hospitals located in other urban and rural areas will be based on the other standardized amount.

Based on the latest available population estimates published by the Bureau of the Census, 63 areas meet the criteria to be defined as large urban areas for FY 2003. These areas are identified in Table 4A.

3. Updating the Average Standardized Amounts

Under section 1886(d)(3)(A) of the Act, we update the average standardized amounts each year. In accordance with section 1886(d)(3)(A)(iv) of the Act, we are updating the large urban areas' and the other areas' average standardized amounts for FY 2003 using the applicable percentage increases specified in section 1886(b)(3)(B)(i) of the Act. Section 1886(b)(3)(B)(i)(XVIII) of the Act specifies that the update factor for the standardized amounts for FY 2003 is equal to the market basket percentage increase minus 0.55 percentage points for hospitals in all areas.

The percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient care. The most recent forecast of the hospital market basket increase for FY 2003 is 3.5 percent. Thus, for FY 2003, the update to the average standardized amounts equals 2.95 percent for hospitals in all areas.

As in the past, we are adjusting the FY 2002 standardized amounts to remove the effects of the FY 2002 geographic reclassifications and outlier payments before applying the FY 2003 updates. That is, we are increasing the standardized amounts to restore the reductions that were made for the effects of geographic reclassification and outliers. We then apply the new offsets to the standardized amounts for outliers and geographic reclassifications for FY 2003.

We do not remove the prior budget neutrality adjustment because, in accordance with section 1886(d)(4)(C)(iii) of the Act, estimated aggregate payments after the changes in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year adjustment, we would not satisfy this condition.

Although the update factors for FY 2003 are set by law, we are required by section 1886(e)(3) of the Act to report to the Congress our initial recommendation of update factors for FY 2003 for both prospective payment hospitals and hospitals excluded from the prospective payment system. We have included our final recommendation on the update factors (which is required by sections 1886(e)(4)(A) and (e)(5)(A) of the Act) in Appendix B to this final rule.

4. Other Adjustments to the Average Standardized Amounts

a. Recalibration of DRG Weights and Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II. of the preamble, we normalized the recalibrated DRG weights by an adjustment factor, so that the average case weight after recalibration is equal to the average case weight prior to recalibration. However, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index.

Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is required by section 4410(b) of Public Law 105–33 to be budget neutral.

In addition, we are required to ensure that any add-on payments for new technology under section 1886(d)(5)(K) of the Act are budget neutral. As discussed in section II.D. of this final rule, we are approving one new technology for add-on payments in FY 2003. We estimate that the total add-on payments for this new technology will be $74.8 million.

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG

reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used FY 2001 discharge data to simulate payments and compared aggregate payments using the FY 2002 relative weights and wage index to aggregate payments using the FY 2003 relative weights and wage index, plus the additional add-on payments for the new technology. The same methodology was used for the FY 2002 budget neutrality adjustment, except for the new technology add-on budget neutrality adjustment. Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.993209. We also adjust the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.994027. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2002 budget neutrality adjustments.

In addition, we will apply these same adjustment factors to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2002. (See the discussion in the September 4, 1990 final rule (55 FR 36073).)

Comment: One commenter questioned this budget neutrality calculation in the proposed rule and pointed out that the total numbers of cases in Table 7A, showing FY 2001 MedPAR records assigned to version 19 GROUPER DRGs, was different than the total number of cases in Table 7B, which shows FY 2001 MedPAR records assigned to version 20 GROUPER DRGs. The commenter noted that a similar discrepancy occurred in the FY 2002 final rule, yet there has been no discrepancy in the past. Based on the discrepancy in total cases, the commenter was concerned that the budget neutrality calculation may be incorrect.

Response: The commenter correctly points out a discrepancy in the source files used to produce Tables 7A and 7B for the FY 2002 final rule and the FY 2003 proposed rule. We have corrected this discrepancy in this final rule. The source of the discrepancy was the removal of statistical outliers for DRG recalibration. Statistical outliers are defined as cases with charges per case and charges per day beyond 3 standard deviations from the DRG mean. In the proposed rule, Table 7A had statistical outliers removed based on the GROUPER version 19 DRG assignment, and Table 7B had statistical outliers removed based on the GROUPER version 20 DRG assignment. In this final rule, we have removed only statistical outliers based on version 20 DRG assignment from both Table 7A and Table 7B.

This discrepancy did not affect the budget neutrality calculation, however. This calculation uses only cases remaining after trimming statistical outliers based on GROUPER version 20 DRG assignment. Payments for these remaining cases are then compared using first their version 19 GROUPER DRG assignment, then their version 20 DRG assignment.

b. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the standardized amount or the wage index, or both.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the acute care hospital inpatient prospective payment system after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. To calculate this budget neutrality factor, we used FY 2001 discharge data to simulate payments, and compared total prospective payments (including IME and DSH payments) prior to any reclassifications to total prospective payments after reclassifications. Based on these simulations, we are applying an adjustment factor of 0.991095 to ensure that the effects of reclassification are budget neutral.

The adjustment factor is applied to the standardized amounts after removing the effects of the FY 2002 budget neutrality adjustment factor. We note that the FY 2003 adjustment reflects FY 2003 wage index and standardized amount reclassifications approved by the MGCRB or the Administrator, and the effects of section 1886(d)(10)(D)(v) of the Act to extend wage index reclassifications for 3 years.

c. Outliers

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases, cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs above a fixed loss cost threshold amount. To determine whether the costs of a case exceed the fixed loss threshold, a hospital's cost-to-charge ratio is applied to the total covered charges for the case to convert the charges to costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the costs above the threshold.

Under section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year must be projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amounts by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amounts applicable to hospitals in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases.

i. FY 2003 outlier fixed loss cost thresholds. For FY 2002, the threshold is equal to the prospective payment rate for the DRG, plus any IME and DSH payments plus $21,025. The marginal cost factor (the percent of costs paid after costs for the case exceed the threshold) is 80 percent.

For FY 2003, we proposed to establish a fixed loss cost outlier threshold equal to the prospective payment rate for the DRG plus any IME and DSH payments, and any add-on payments for new technology, plus $33,450. This single threshold would be applicable for cases to qualify for both operating and capital outlier payments. We proposed to maintain the marginal cost factor at 80 percent.

To calculate the FY 2003 outlier thresholds, we simulated payments by applying FY 2003 rates and policies to the March 2002 update of the FY 2001 MedPAR file and the March 2002 update of the Provider-Specific File. Therefore, it was necessary to inflate the charges on the MedPAR claims by 2 years, from FY 2001 to FY 2003, in order to determine the appropriate FY 2003 thresholds.

Previously, inflation factors have been calculated by measuring the percent change in costs using the two most recent available cost report files. For example, the FY 2002 threshold was determined using the rate of cost increase measured using costs from hospitals' FY 1998 and FY 1999 cost reports. However, at the time of the proposed rule, the FY 2000 cost reports were not available to produce an updated cost inflation factor due to processing delays associated with implementing the hospital outpatient prospective payment system.

As discussed in the May 9, 2002 proposed rule, rather than use the rate of cost increase from hospitals' FY 1998 and FY 1999 cost reports to project the rate of increase from FY 2001 to FY 2003, we proposed to use a 3-year moving average of the rate of change in costs for prior years to estimate the annual rates of inflation from FY 2001 to FY 2003. The calculation was discussed thoroughly in the proposed rule (67 FR 31510).

Based on this methodology, we proposed a 2-year cost inflation factor of 15.0 percent to inflate FY 2001 charges to FY 2003, determined by multiplying the annual projected inflation factors for FYs 2002 and 2003 of 1.0655 and 1.0793.

We pointed out that, using actual FY 2001 cases, our analysis indicated that this 3-year moving average methodology would have resulted in FY 2002 outlier payments very close to 5.1 percent of total operating DRG payments and outlier payments.

Comment: Several commenters stated that the proposed 59 percent increase in the outlier threshold is an enormous increase based on old data and a new methodology, and as a result, puts hospitals at even greater risk for high-cost cases. One commenter wrote that this type of unpredictability makes sound management difficult.

The commenters also believed that the proposed outlier policy, if implemented in a budget neutral manner, has the effect of reducing hospital payments by 1.87 percent, nearly wiping out any inflationary increase paid through the market basket increase.The commenters stated that, without more recent data and better rationale, the outlier threshold should remain unchanged at the FY 2002 level of $21,025.

Response: Our objective in setting the outlier threshold is to set it at a level that is projected to result in outlier payments during the upcoming Federal fiscal year that are equal to 5.1 percent of operating DRG payments. In accordance with section 1886(d)(3)(B) of the Act, we reduce the standardized amounts by 5.1 percent to account for the projected 5.1 percent paid to outliers. This adjustment is intended to ensure that outlier payments are budget neutral: Total payments after making outlier payments are equal to what total payments would have been without making any outlier payments. Therefore, if our projections of outlier payments are perfectly accurate, there is no net change in total hospital payments related to outlier policy.

We believe the reference to reducing hospital payments by 1.87 percent relates to the fact that, for FY 2002, outlier payments will be greater than 5.1 percent of total DRG payments, and if outlier payments are projected to equal 5.1 percent of total DRG payments in FY 2003, hospitals will not receive the additional payments they otherwise would if outlier payments exceeded 5.1 percent. The statute requires that the outlier offset to the average standardized amounts equal the projected proportion of outlier payments relative to total operating DRG payments. Therefore, if we offset the average standardized amounts by 5.1 percent to account for outlier payments, we must set the outlier threshold at a level we project will result in outlier payments equal to 5.1 percent of total operating DRG payments.

Moreover, we believe that in order to maintain the fiscal integrity of the Medicare Trust Fund, we must set the FY 2003 outlier threshold so that, based on our best estimate, the proportion of FY 2003 outlier payments relative to total DRG payments is projected to equal the offset of the average standardized amounts.

As discussed in further detail below, we now estimate FY 2002 outlier payments to be 6.9 percent of total DRG payments, using the FY 2002 threshold of $21,025. Therefore, we estimate that we will be paying approximately $1.5 billion more in outlier payments during FY 2002 than we would have if our outlier projections had been perfectly accurate (outlier payments 1.9 percentage points higher relative to total DRG payments of approximately $76 billion). The table below demonstrates that actual outlier payments since 1997 have exceeded the 5.1 percent offset by an aggregate of 11.2 percentage points, equating with approximately $8.5 billion in higher than anticipated payments. However, analysis over a longer time period demonstrates that years in which CMS has paid more than projected in outlier payments are offset by years in which CMS has paid less than projected.

Year	Payments in excess of 5.1 percent (percentage points)
1997	0.4
1998	1.4
1999	2.5
2000	2.5
2001	2.6
2002	1.8

Based on available information (which was not available at the time we set the FY 2003 outlier thresholds), we now estimate that an outlier threshold of $30,525 would have resulted in outlier payments equal to 5.1 percent of total DRG payments for FY 2002. Therefore, barring any drastic reductions in hospital charges per case, maintaining the FY 2003 fixed loss outlier threshold at $21,025, while offsetting the standardized amount by only 5.1 percent, would almost certainly guarantee that FY 2003 total payments after outlier payments and the offset would exceed what total payments would have been without making any outlier payments or offset.

Comment: Numerous commenters added that the proposed methodology for determining the estimate of cost inflation is flawed and, as a result, the new threshold is too high. The commenters expressed concern that increasing the threshold too fast will seriously undermine hospitals' ability to continue to care for high-cost frail and elderly patients.

The commenters stated that the proposed 2-year cost inflation factor of 15.0 percent from FY 2001 to FY 2003 is more than triple the rate of change of cost inflation in FY 1999. The commenters also stated that this increase is also markedly different and significantly higher than all other government projections of cost inflation. For instance, they pointed out that, in its March 2002 report, MedPAC measured hospital cost inflation at 4.8 percent for the time period FY 2001 to FY 2003; the Office of Management and Budget has projected cost inflation for the overall economy at a rate of 2.2 percent for FY 2003; and CMS' market basket for that time period is a 6.6 percent increase.

Several commenters focused on the fact that, rather than proposing to calculate the inflation factor based on an annual rate of change, we proposed to calculate it using the difference in the annual rate of change (second derivative). The commenters submitted analysis indicating this proposed methodology was more volatile in its estimates than alternative approaches. In addition, the commenters stated that our data were outdated and therefore unreliable.

The commenters proposed using one of three alternatives:

- Three-year moving average of annual rates of change in costs rather than a 3-year average of the differences in the annual rates of change in costs (as proposed). The projected increase in hospital cost inflation from FY 2001 to FY 2003 using this method would be 4.1 percent.
- CMS' usual method in predicting cost inflation, but substituting a 4-year lag in data rather than the typical 3-year lag due to the lack of FY 2000 cost reports. The projected increase in hospital cost inflation from FY 2001 to FY 2003 would be 4.8 percent.
- Changes as measured in the hospital market basket index. The projected increase in hospital cost inflation from FY 2001 to FY 2003 would be 7.1 percent.

The commenters stated that the alternative that most closely approximates CMS' usual method is the 4-year lag approach. The commenters also recognized that the simulations of the market basket index approach they submitted tracks most closely with actual cost increases. The commenters stated that this method would result in a new outlier threshold between $26,254 and $27,810, which the commenters believe is a much more realistic increase.

One commenter noted that determining the outlier threshold is dependent not only on changes in costs per case, but is also dependent on hospital charges and cost-to-charge ratios.

Response: Our proposed methodology took into account that the most recent cost data we had available was approximately 3 years old by including a factor to measure the rate of growth in the annual change in costs per case. Using data from hospitals' cost reports, we calculated average annual rates of change to project cost growth from FYs 1999 through 2003. We believe this approach was preferable to a simple average rate of change when projecting over a 4-year time span because, by including a factor to measure the rate of change we account for the observed trend in cost growth over recent periods. We do not dispute that this methodology results in inflation factors higher than other estimates, including the market basket used to update the acute inpatient prospective payment system. However, we point out that our analysis in the proposed rule showed that, if this methodology had been used to estimate the threshold for FY 2002, it would have resulted in FY 2002 outlier payments much closer to 5.1 percent of total DRG payments than we are currently estimating (67 FR 31510).

Nevertheless, we understand the commenters' concerns that our methodology to estimate cost inflation for purposes of setting the outlier threshold is much higher than other, more established methodologies and we considered the alternatives suggested by the commenters. Each of the three alternative are based on projecting cost increases.

As noted above, commenters indicated they believe a FY 2003 threshold between $26,254 and $27,810 would be realistic. However, we believe, based on our analysis of MedPAR data, that this threshold would be significantly inaccurate. To illustrate, we used actual MedPAR data for the past 2.5 years to determine what thresholds would have resulted in a 5.1 percent outlier payout for FYs 2000, 2001 and 2002.

Fiscal year	Threshold actually applied	Threshold that would have paid out 5.1 percent	Actual payout percentage
2000	$14,050	$21,825	7.6
2001	17,550	26,200	7.7
2002*	21,025	30,525*	6.9

*Using March 2002 Update of Fiscal Year 2002 MedPAR Cases.

This table shows that, had we set the threshold each of the last 3 fiscal years at a level that would have paid out 5.1 percent based on data now available, the FY 2002 threshold would have actually been $30,525. Based on this analysis, we believe a threshold of no more than $27,810, as suggested by the commenters, would be likely to result in payments in excess of 5.1 percent.

Outlier payments are determined by multiple variables that change at different rates over time. As described above, to determine whether a case qualifies as an outlier, the hospital's cost-to-charge ratio is applied to the covered charges (which are adjusted for the area wage index applicable to the area where the hospital is located) of a case to estimate the costs. The estimated costs for the case are then compared to the outlier threshold to determine whether the case qualifies for outlier payments.

Based on our analysis above, we believe that, due to current trends in hospital charging practices, using inflation factors based on annual cost growth results in underestimating the percentage of outlier payments. That is, if charges are growing at a faster rate than costs, inflating FY 2001 charges by the observed rate of change in costs will underestimate FY 2003 charges, thereby resulting in outlier payments greater than 5.1 percent. Therefore, we analyzed the rate of change in covered charges per case over the past 3 years. Because charge data are available from claims data in the MedPAR file, they are more up-to-date than cost data taken from the cost reports.

FY	Covered charge/case	Percentage change in charge/case
1999	$15,215	
2000	16,376	7.63
2001	18,015	10.00

This table illustrates the substantial increase recently in the growth of charges, indicating that charges have indeed been increasing faster than costs. Because charges serve as the basis to estimate costs for purposes of identifying outlier cases, higher than expected increases in charges would lead to more cases qualifying for outlier payments than expected (and more of the costs of qualifying cases in excess of the threshold).

Over time, cost-to-charge ratios will reflect the differential increase in charges. However, due to the delay in processing the FY 2000 cost reports, combined with the dramatically different rates of change in charges and costs, we believe it is appropriate, at least as far as determining the outlier thresholds for FY 2003, to change from our past methodology of basing the inflation factor on the rate of change in costs, and instead rely on the rate of change in charges. Therefore, we are not adopting our proposed methodology.

Instead, we have determined that, for purposes of setting a FY 2003 outlier threshold that we project will result in outlier payments of 5.1 percent of total DRG payments, the most appropriate methodology to use is to inflate charges using a 2-year average annual rate of change in charges per case. The 2-year average annual rate of change in charges per case from FY 1999 to FY 2000, and from FY 2000 to FY 2001, is 8.8199 percent annually, or 17.6398 percent over 2 years. Applying this charge inflation factor to FY 2001 cases results in a fixed loss outlier threshold of $33,560.

We believe inflating charges by the 2-year average annual rate of change in charges per case is an appropriate revision to our prior inflation methodology used to set the threshold. That is, our analysis described above indicates that a 2-year average annual rate of change based on charges results in a threshold that is more consistent with what our analysis indicates recent thresholds would have resulted in actual outlier payments approximating 5.1 percent of actual total operating DRG payments. In addition, our analysis above demonstrates that charges have been growing at a much faster rate than recent estimates of cost growth, indicating that the average rate of change in charges will produce a more appropriate inflation factor at this time. We have selected a 2-year average rate of change in charges (from FY 1999 to FY 2000 and from FY 2000 to FY 2001) rather than simply a 1-year rate of change in order to account for the greater variability of charges (due to the fact that hospitals have greater latitude in setting their charges than they do over their costs). We would point out that this analysis is based on recent data and does not reflect upon previous analysis used to support the use of cost inflation factors used in the Medicare cost reports.

Using this revised methodology for setting the charge inflation factors for FY 2003, we are establishing a fixed loss cost outlier threshold equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $33,560. This single threshold would be applicable to qualify for both operating and capital outlier payments. We are also maintaining the marginal cost factor for cost outliers at 80 percent.

Comment: Two commenters recommended that we increase the FY 2002 threshold by the market basket inflation factor, then develop a new threshold using our previous cost inflation methodology when FY 2000 cost reports come available later this year.

Response: Based on our analysis of where prior years' thresholds would have been set if we knew at the time we set the thresholds what we know now, and our analysis showing the higher rate of change in charges than in costs, we are revising our methodology to establish the FY 2003 outlier thresholds to reflect the rate of change in charges. We believe this will establish the thresholds at an appropriate level using more recent data. Therefore, we are not accepting the commenters' recommendation.

Comment: Some commenters predicted that, as a result of the large increase in the threshold from FY 2002, outlier payments would fall well below 5.1 percent.

Response: We have taken the commenters' concerns and our further analysis into account in our methodology to set the FY 2003 threshold. Based on our analysis as described above, we disagree with the commenters' prediction.

Comment: One commenter attributed the high percentage of outlier payments relative to DRG payments to the increasing costs of medical technology, for which the commenter argued that there is no effective payment solution.

Response: Our analysis indicates the higher than estimated outlier payments are attributable to charges rising faster than our inflation estimates. This may be associated with increasing costs and utilization of medical technology, as the commenter suggested. This effect would eventually be reflected in the DRG weights and the market basket estimate.

However, we would point out that our analysis above indicates that charges are rising much faster than costs. This would indicate that costs estimated by applying cost-to-charge ratios from past periods to charges from current periods would result in estimated costs in excess of actual costs. Therefore, we disagree that rising costs due to new technology is the reason outlier payments have been higher than projected.

Comment: Some commenters argued that the delay in processing cost reports is interrupting the gradually declining trend in cost-to-charge ratios, leading to higher cost estimates than anticipated.

Response: Our analysis shows that, despite the delay in processing cost reports alluded to above, the average cost-to-charge ratios have continued to decline. We note there is always a lag between the timeframe from which the cost-to-charge ratios are taken and the period to which they are applied to charges. We do not have any evidence that the higher than expected outlier payments result from any extra lag in updating cost-to-

charge ratios due to the delay in processing the cost reports.

Comment: Some commenters referenced a joint letter from CMS' Center for Medicare Management, Office of Financial Management, issued April 22, 2002, on the issue of the correct calculation of hospital cost-to-charge ratios, as indicative of potential erroneous cost-to-charge ratios influencing the calculation of the outlier threshold.

Response: The joint letter clarified instructions to all fiscal intermediaries on calculating the cost-to-charge ratios in response to isolated instances where we were made aware they had been calculated incorrectly. We have examined the cost-to-charge ratios and do not believe the issue addressed in the joint letter is systemic, and therefore, it should not materially affect our outlier threshold calculations.

Comment: One commenter recommended increasing the estimated outlier payment percentage from 5.1 percent to 6.0 percent, the upper bound permissible under the statute. The commenter believed the proposed outlier change would cause an inequitable redistribution and that increasing the outlier target would address this inequity.

Response: Although reducing the outlier threshold would result in a higher outlier payout, and we have authority under section 1886(d)(5)(A)(iv) of the Act to set an outlier target of up to 6.0 percent, we do not believe this approach would be appropriate. As noted previously, section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amounts by the projected proportion of total DRG payments made to outlier cases. Therefore, adopting this suggestion would result in lower standardized amounts for all cases, reducing payments for hospitals that do not generally receive as high a proportion of outlier payments as other hospitals as a result of the lower standardized amount. These low-outlier hospitals would be negatively impacted by reducing the standardized amount without the benefit of continued high outlier payments.

Comment: Commenters also suggested reducing the marginal cost factor below 80 percent. One commenter suggested raising the marginal cost factor from 80 percent to 90 percent. This commenter stated such a change would redistribute the negative impact of increasing the threshold in a more equitable manner.

Response: Reducing the marginal cost factor would result in a lower outlier threshold (so more cases would qualify for outlier payments) but would also result in lower outlier payments per outlier case. While we considered this approach to alleviate the impact of the proposed increase in the outlier threshold, we decided not to adopt it without further analysis (the commenter presented no assessment of the impacts of such a change, for example). We note that the current 80 percent marginal cost factor was established for FY 1994 (from 75 percent) to further focus Medicare's cost outlier payments on the costliest cases (59 FR 45367). This change was consistent with a recommendation by the Prospective Payment Assessment Commission (MedPAC's predecessor) based on its analysis of outlier policy. We believe it would be necessary to conduct further analysis of the impacts of changing the marginal cost factor before making such a change in the marginal cost factor. Conversely, increasing the marginal cost factor would result in either raising the outlier threshold (which means fewer cases would qualify for outlier payments) or raising the offset to the standardized amount, or both. We believe that an 80 percent marginal cost factor and 5.1 percent outlier target appropriately target payments to extremely high cost cases and, at the same time, provide adequate compensation to nonoutlier cases.

ii. Other changes concerning outliers. In accordance with section 1886(d)(5)(A)(iv) of the Act, we calculated outlier thresholds so that outlier payments are projected to equal 5.1 percent of total operating DRG payments plus outlier payments. In accordance with section 1886(d)(3)(B), we reduced the FY 2003 standardized amounts by the same percentage to account for the projected proportion of payments paid to outliers.

As stated in the September 1, 1993 final rule (58 FR 46348), we establish outlier thresholds that are applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common set of thresholds resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2003 will result in outlier payments equal to 5.1 percent of operating DRG payments and 5.4 percent of capital payments based on the Federal rate.

The proposed outlier adjustment factors to be applied to the standardized amounts for FY 2003 were as follows:

	Operating standardized amounts	Capital federal rate
National	0.949004	0.945957
Puerto Rico	0.982910	0.980994

Based on simulations of payments using updated data, the final outlier adjustment factors applied to the standardized amounts for FY 2003 are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.946924
Puerto Rico	0.981651	0.979669

As in the proposed rule, we apply the outlier adjustment factors after removing the effects of the FY 2002 outlier adjustment factors on the standardized amounts.

To determine whether a case qualifies for outlier payments, we apply hospital-specific cost-to-charge ratios to the total covered charges for the case. Operating and capital costs for the case are calculated separately by applying separate operating and capital cost-to-charge ratios, then these costs are combined to compare with the fixed-loss outlier threshold.

For those hospitals for which the fiscal intermediary computes operating cost-to-charge ratios lower than 0.194 or greater than 1.258, or capital cost-to-charge ratios lower than 0.012 or greater than 0.163, statewide average ratios would be used to calculate costs to determine whether a hospital qualifies for outlier payments.[1] Table 8A in section V. of this Addendum contains the updated statewide average operating cost-to-charge ratios for urban hospitals and for rural hospitals for which the fiscal intermediary is unable to compute a hospital-specific cost-to-charge ratio within the above range. These statewide average ratios replace the ratios published in the August 1, 2001 final rule (66 FR 40083). Table 8B contains comparable statewide average capital cost-to-charge ratios. We note that the cost-to-charge ratios in Tables 8A and 8B will be used during FY 2003 when hospital-specific cost-to-charge ratios based on the latest settled cost report are either not available or are outside the ranges noted above.

iii. FY 2001 and FY 2002 outlier payments. In the August 1, 2001 final rule (66 FR 39942), we stated that, based on available data, we estimated that actual FY 2001 outlier payments would be approximately 6.2 percent of actual total DRG payments. This was computed based on simulations using the March 2001 update of the Provider-Specific File and the March 2001 update of the FY 2000 MedPAR file (discharge data for FY 2000 bills). That is, the estimate of actual outlier payments did not reflect actual FY 2001 bills but instead reflected the application of FY 2001 rates and policies to available FY 2000 bills.

Our current estimate, using available FY 2001 bills, is that actual outlier payments for FY 2001 were approximately 7.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2001, the percentage of actual outlier payments relative to actual total payments is higher than we projected before FY 2001 (and thus exceeds the percentage by which we reduced the standardized amounts for FY 2001). Nevertheless, consistent with the policy and statutory interpretation we have maintained since the inception of the acute care hospital inpatient prospective payment system, we do not plan to recoup money and make retroactive adjustments to outlier payments for FY 2001.

We currently estimate that actual outlier payments for FY 2002 will be approximately 6.9 percent of actual total DRG payments, 1.8 percentage points higher than the 5.1 percent we projected in setting outlier policies for FY 2002. This estimate is based on simulations using the March 2001 update of the Provider-Specific File and the March 2001 update of the FY 2001 MedPAR file (discharge data for FY 2001 bills). We used these data to calculate an estimate of the actual outlier percentage for FY 2002 by applying FY 2002 rates and policies to available FY 2001 bills.

5. FY 2003 Standardized Amounts

The adjusted standardized amounts are divided into labor and nonlabor portions.

[1] This range represents 3.0 standard devitations (plus or minus) from the mean of the log distribution of cost-to-charge ratios for all hospitals.

Table 1A contains the two national standardized amounts that are applicable to all hospitals, except hospitals in Puerto Rico. As described in section II.A.1. of this Addendum, we are not revising the labor share of the national standardized amount from 71.1 percent.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount and the national other standardized amount (as set forth in Table 1A). The labor and nonlabor portions of the national average standardized amounts for Puerto Rico hospitals are set forth in Table 1C. This table also includes the Puerto Rico standardized amounts. The labor share applied to the Puerto Rico standardized amount is 71.3 percent.

B. Adjustments for Area Wage Levels and Cost of Living

Tables 1A and 1C, as set forth in this Addendum, contain the labor-related and nonlabor-related shares that will be used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of this preamble, we discuss the data and methodology for the FY 2003 wage index. The wage index is set forth in Tables 4A, 4B, 4C, and 4F of this Addendum.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act authorizes an adjustment to take into account the unique circumstances of hospitals in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. For FY 2003, we are adjusting the payments for hospitals in Alaska and Hawaii by multiplying the nonlabor portion of the standardized amounts by the appropriate adjustment factor contained in the table below.

TABLE OF COST-OF-LIVING ADJUSTMENT FACTORS, ALASKA AND HAWAII HOSPITALS

Alaska—All areas	1.25
Hawaii:	
County of Honolulu	1.25
County of Hawaii	1.165
County of Kauai	1.2325
County of Maui	1.2375
County of Kalawao	1.2375

(The above factors are based on data obtained from the U.S. Office of Personnel Management.)

C. DRG Relative Weights

As discussed in section II. of the preamble, we have developed a classification system for all hospital discharges, assigning them into DRGs, and have developed relative weights for each DRG that reflect the resource utilization of cases in each DRG relative to Medicare cases in other DRGs. Table 5 of section V. of this Addendum contains the relative weights that we will use for discharges occurring in FY 2003. These factors have been recalibrated as explained in section II. of the preamble.

D. Calculation of Prospective Payment Rates for FY 2003

General Formula for Calculation of Prospective Payment Rates for FY 2003

The operating prospective payment rate for all hospitals paid under the acute-care, short-term inpatient prospective payment system located outside of Puerto Rico, except SCHs and MDHs, equals the Federal rate based on the amounts in Table 1A.

The prospective payment rate for SCHs and MDHs equals the higher of the applicable Federal rate from Table 1A or the hospital-specific rate as described below. The prospective payment rate for Puerto Rico equals 50 percent of the Puerto Rico rate plus 50 percent of the national rate from Table 1C.

1. Federal Rate

For discharges occurring on or after October 1, 2002 and before October 1, 2003, except for SCHs, MDHs, and hospitals in Puerto Rico, payment under the acute-care inpatient prospective payment system is based exclusively on the Federal national rate.

The payment amount is determined as follows:

Step 1—Select the appropriate average standardized amount considering the location of the hospital (large urban or other) (see Table 1A in section V. of this Addendum).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified (see Tables 4A, 4B, and 4C of section V. of this Addendum).

Step 3—For hospitals in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the appropriate cost-of-living adjustment factor.

Step 4—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if appropriate, under Step 3).

Step 5—Multiply the final amount from Step 4 by the relative weight corresponding to the appropriate DRG (see Table 5 of section V. of this Addendum).

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or, for FY 2003, 75 percent of the updated hospital-specific rate based on FY 1996 costs per discharge, plus the greater of 25 percent of the updated FY 1982 or FY 1987 hospital-specific rate or 25 percent of the Federal DRG payment rate.

Section 1886(d)(5)(G) of the Act provides that MDHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate or the Federal rate plus 50 percent of the difference between the Federal rate and the greater of the updated hospital-specific rate based on FY 1982 and FY 1987 cost per discharge. MDHs do not have the option to use their FY 1996 hospital-specific rate.

Hospital-specific rates have been determined for each of these hospitals based on either the FY 1982 cost per discharge, the FY 1987 cost per discharge or, for SCHs, the FY 1996 cost per discharge. For a more detailed discussion of the calculation of the hospital-specific rates, we refer the reader to the September 1, 1983 interim final rule (48 FR 39772); the April 20, 1990 final rule with comment (55 FR 15150); the September 4, 1990 final rule (55 FR 35994); and the August 1, 2000 final rule (65 FR 47082). In addition, for both SCHs and MDHs, the hospital-specific rate is adjusted by the budget neutrality adjustment factor (that is, by 0.994027) as discussed in section II.A.4.a. of this Addendum. The resulting rate is used in determining the payment rate an SCH or MDH would be paid for its discharges beginning on or after October 1, 2002.

b. Updating the FY 1982, FY 1987, and FY 1996 Hospital-Specific Rates for FY 2003

We are increasing the hospital-specific rates by 2.95 percent (the hospital market basket percentage increase minus 0.55 percentage points) for SCHs and MDHs for FY 2003. Section 1886(b)(3)(C)(iv) of the Act provides that the update factor applicable to the hospital-specific rates for SCHs equal the update factor provided under section 1886(b)(3)(B)(iv) of the Act, which, for SCHs in FY 2003, is the market basket rate of increase minus 0.55 percentage points. Section 1886(b)(3)(D) of the Act provides that the update factor applicable to the hospital-specific rates for MDHs equals the update factor provided under section 1886(b)(3)(B)(iv) of the Act, which, for FY 2003, is the market basket rate of increase minus 0.55 percentage points.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning On or After October 1, 2002 and Before October 1, 2003

a. Puerto Rico Rate

The Puerto Rico prospective payment rate is determined as follows:

Step 1—Select the appropriate adjusted average standardized amount considering the large urban or other designation of the hospital (see Table 1C of section V. of the Addendum).

Step 2—Multiply the labor-related portion of the standardized amount by the appropriate Puerto Rico-specific wage index (see Table 4F of section VI. of the Addendum).

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4—Multiply the result in Step 3 by 50 percent.

Step 5—Multiply the amount from Step 4 by the appropriate DRG relative weight (see Table 5 of section V. of the Addendum).

b. National Rate

The national prospective payment rate is determined as follows:

Step 1—Multiply the labor-related portion of the national average standardized amount (see Table 1C of section V. of the Addendum) by the appropriate national wage index (see Tables 4A and 4B of section VI. of the Addendum).

Step 2—Add the amount from Step 1 and the nonlabor-related portion of the national average standardized amount.

Step 3—Multiply the result in Step 2 by 50 percent.

Step 4—Multiply the amount from Step 3 by the appropriate DRG relative weight (see Table 5 of section V. of the Addendum).

The sum of the Puerto Rico rate and the national rate computed above equals the prospective payment for a given discharge for a hospital located in Puerto Rico.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2003

The prospective payment system for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period and during a 10-year transition period extending through FY 2001, acute care hospital inpatient capital-related costs were paid on the basis of an increasing proportion of the capital prospective payment system Federal rate and a decreasing proportion of a hospital's historical costs for capital.

The basic methodology for determining Federal capital prospective rates is set forth in regulations at §§ 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2003, which will be effective for discharges occurring on or after October 1, 2002. The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.324(b) and under § 412.304(c)(2)) are paid based on 100 percent of the capital Federal rate.

For FY 1992, we computed the standard Federal payment rate for capital-related costs under the prospective payment system by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. Also, § 412.308(c)(2) provides that the Federal rate is adjusted annually by a factor equal to the estimated proportion of outlier payments under the Federal rate to total capital payments under the Federal rate. In addition, § 412.308(c)(3) requires that the Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for (regular and special) exceptions under § 412.348. Furthermore, § 412.308(c)(4)(ii) requires that the Federal rate be adjusted so that the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor are budget neutral. For FYs 1992 through 1995, § 412.352 required that the Federal rate also be adjusted by a budget neutrality factor so that aggregate payments for inpatient hospital capital costs were projected to equal 90 percent of the payments that would have been made for capital-related costs on a reasonable cost basis during the fiscal year. That provision expired in FY 1996. Section 412.308(b)(2) describes the 7.4 percent reduction to the rate that was made in FY 1994, and § 412.308(b)(3) describes the 0.28 percent reduction to the rate made in FY 1996 as a result of the revised policy of paying for transfers. In the FY 1998 final rule with comment period (62 FR 45966), we implemented section 4402 of Public Law 105–33, which requires that, for discharges occurring on or after October 1, 1997, and before October 1, 2002, the unadjusted standard Federal rate is reduced by 17.78 percent. As we explained in section VI.D. of the preamble of this final rule, a small part of that reduction will be restored effective October 1, 2002.

To determine the appropriate budget neutrality adjustment factor and the regular exceptions payment adjustment during the 10-year transition period, we developed a dynamic model of Medicare inpatient capital-related costs, that is, a model that projected changes in Medicare inpatient capital-related costs over time. With the expiration of the budget neutrality provision, the capital cost model was only used to estimate the regular exceptions payment adjustment and other factors. As we explained in the August 1, 2001 final rule (66 FR 39911), beginning in FY 2003 an adjustment for regular exceptions is no longer necessary because regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001 (see § 412.348(b)). Since payments are no longer being made under the regular exceptions policy in FY 2003, we are no longer using the capital cost model. The capital cost model and its application during the transition period are described in Appendix B of the August 1, 2001 final rule (66 FR 40099).

In accordance with section 1886(d)(9)(A) of the Act, under the prospective payment system for acute care hospital inpatient operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Prior to FY 1998, hospitals in Puerto Rico were paid a blended rate that consisted of 75 percent of the applicable standardized amount specific to Puerto Rico hospitals and 25 percent of the applicable national average standardized amount. However, effective October 1, 1997, as a result of section 4406 of Public Law 105–33, operating payments to hospitals in Puerto Rico are based on a blend of 50 percent of the applicable standardized amount specific to Puerto Rico hospitals and 50 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges on or after October 1, 1997, we compute capital payments to hospitals in Puerto Rico based on a blend of 50 percent of the Puerto Rico rate and 50 percent of the Federal rate.

Section 412.374 provides for the use of this blended payment system for payments to Puerto Rico hospitals under the prospective payment system for acute care hospital inpatient capital-related costs. Accordingly, for capital-related costs, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital.

A. Determination of Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the final rule published in the **Federal Register** on August 1, 2001 (66 FR 39947), we established a Federal rate of $390.74 for FY 2002. As a result of the changes to the factors used to establish the Federal rate that are explained in this addendum, the FY 2003 Federal rate is $407.01.

In the discussion that follows, we explain the factors that were used to determine the FY 2003 Federal rate. In particular, we explain why the FY 2003 Federal rate has increased 4.2 percent compared to the FY 2002 Federal rate. We also estimate aggregate capital payments will increase by 5.81 percent during this same period. This increase is primarily due to the increase in the number of hospital admissions and the increase in case-mix. This increase in capital payments is slightly more than last year (4.27 percent) mostly due to the restoration of the 2.1 percent reduction to the capital Federal rate (see section VI.D. of the preamble of this final rule).

Total payments to hospitals under the prospective payment system are relatively unaffected by changes in the capital prospective payments. Since capital payments constitute about 10 percent of hospital payments, a 1 percent change in the capital Federal rate yields only about 0.1 percent change in actual payments to hospitals. Aggregate payments under the capital prospective payment system are estimated to increase in FY 2003 compared to FY 2002.

1. Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and other factors. The update framework consists of a CIPI and several policy adjustment factors.

Specifically, we have adjusted the projected CIPI rate of increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed rule reflected an update factor for FY 2003 under that framework of 1.1 percent, based on data available at that time. Under the update framework, the final update factor for FY 2003 is 1.1 percent. This update factor is based on a projected 0.7 percent increase in the CIPI, a 1.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a −0.3 percent adjustment for the FY 2001 DRG reclassification and recalibration, and a forecast error correction of −0.3 percent. We explain the basis for the FY 2003 CIPI projection in section III.C. of this Addendum. Below we describe the policy adjustments that have been applied.

The case-mix index is the measure of the average DRG weight for cases paid under the acute care hospital inpatient prospective payment system. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes (''real'' case-mix change);
- Changes in hospital coding of patient records result in higher weight DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in coding behavior that result in assignment of cases to higher weighted DRGs but do not reflect higher resource requirements. In the update framework for the prospective payment system for operating costs, we adjust the update upwards to allow for real case-mix change, but remove the effects of coding changes on the case-mix index. We also remove the effect on total payments of prior year changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than patient severity. (For example, we adjusted for the effects of the FY 2001 DRG reclassification and recalibration as part of our update for FY 2003.) We have adopted this case-mix index adjustment in the capital update framework as well.

For FY 2003, we are projecting a 1.0 percent total increase in the case-mix index. We estimate that real case-mix increase will equal 1.0 percent in FY 2003. Therefore, the net adjustment for case-mix change in FY 2003 is 0.0 percentage points.

We estimate that FY 2001 DRG reclassification and recalibration will result in a 0.3 percent change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are making a −0.3 percent adjustment for DRG reclassification and recalibration in the update for FY 2003 to maintain budget neutrality.

The capital update framework contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage points or more. There is a 2-year lag between the forecast and the measurement of the forecast error. A forecast error of −0.3 percentage points was calculated for the FY 2001 update. That is, current historical data indicate that the forecasted FY 2001 CIPI used in calculating the FY 2001 update factor (0.9 percent) overstated the actual realized price increases (0.6 percent) by 0.3 percentage points. This over-prediction was due to prices from municipal bond yields declining faster than originally expected. Therefore, we are making a −0.3 percent adjustment for forecast error in the update for FY 2003.

Under the capital prospective payment system framework, we also make an adjustment for changes in intensity. We calculate this adjustment using the same methodology and data as in the framework for the operating prospective payment system. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, changes in within-DRG severity, and expected modification of practice patterns to remove cost-ineffective services.

We calculate case-mix constant intensity as the change in total charges per admission, adjusted for price level changes (the CPI for hospital and related services), and changes in real case-mix. The use of total charges in the calculation of the intensity factor makes it a total intensity factor, that is, charges for capital services are already built into the calculation of the factor. Therefore, we have incorporated the intensity adjustment from the operating update framework into the capital update framework. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and to the combination of quality-enhancing new technologies and within-DRG complexity, we assume, as in the revised operating update framework, that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity to allow for within-DRG severity increases and the adoption of quality-enhancing technology.

For FY 2003, we have developed a Medicare-specific intensity measure based on a 5-year average, using FY 1997 through 2001 data. In determining case-mix constant intensity, we found that observed case-mix increase was 0.3 percent in FY 1997, −0.4 percent in FY 1998, −0.3 percent in FY 1999, −0.7 in FY 2000, and −0.3 percent in FY 2001. Past studies of case-mix change by the RAND Corporation (''Has DRG Creep Crept Up? Decomposing the Case Mix Index Change Between 1987 and 1988'' by G. M. Carter, J. P. Newhouse, and D. A. Relles, R–4098–HCFA/ProPAC (1991)) suggest that real case-mix change was not dependent on total change, but was usually a fairly steady 1.0 to 1.4 percent per year. We use 1.4 percent as the upper bound because the RAND study did not take into account that hospitals may have induced doctors to document medical records more completely in order to improve payment. Following that study, we consider up to 1.4 percent of observed case-mix change as real for FY 1997 through FY 2001. Since we did not find an increase in case-mix outside of the range of 1.0 to 1.4 percent, we believe that all of the observed case-mix increase for FYs 1997 through 2001 is real. Therefore, there was no need to employ the upper bound of 1.0 and 1.4 supported by the RAND study as we have done in the past since we did not find an increase in case-mix that was in excess of our estimate of real case-mix increase.

We calculate case-mix constant intensity as the change in total charges per admission, adjusted for price level changes (the CPI for hospital and related services), and changes in real case-mix. We estimate that case-mix constant intensity increased by an average of 1.0 percent during FYs 1997 through 2001, for a cumulative increase of 5.2 percent, given estimates of real case-mix of 0.3 percent for FY 1997, −0.4 percent for FY 1998, −0.3 percent for FY 1999, −0.7 percent for FY 2000, and −0.3 percent for FY 2001. Since we estimate that intensity has increased during that period, the intensity adjustment for FY 2003 is 1.0 percent.

Above we described the basis of the components used to develop the 1.1 percent final capital update factor for FY 2003 as shown in Table 1 below.

TABLE 1.—CMS'S FY 2003 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index	0.7
Intensity:	1.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	−1.0
Real Across DRG Change	1.0
Subtotal	0.0
Effect of FY 2001 Reclassification and Recalibration	−0.3
Forecast Error Correction	−0.3
Total Update	1.1

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and

inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related prospective payment system payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating DRG payments.

In the August 1, 2001 final rule, we estimated that outlier payments for capital in FY 2002 would equal 5.76 percent of inpatient capital-related payments based on the Federal rate (66 FR 39948). Accordingly, we applied an outlier adjustment factor of 0.9424 to the Federal rate. Based on the thresholds as set forth in section II.A.4.c. of this Addendum, we estimate that outlier payments for capital will equal 5.31 percent of inpatient capital-related payments based on the Federal rate in FY 2003. Therefore, we are establishing an outlier adjustment factor of 0.9469 to the Federal rate. Thus, the projected percentage of capital outlier payments to total capital standard payments for FY 2003 is lower than the percentage for FY 2002.

The outlier reduction factors are not built permanently into the rates; that is, they are not applied cumulatively in determining the Federal rate. Therefore, the net change in the outlier adjustment to the Federal rate for FY 2003 is 1.0048 (0.9469/0.9424). The outlier adjustment increases the FY 2003 Federal rate by 0.48 percent compared with the FY 2002 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the Geographic Adjustment Factor

Section 412.308(c)(4)(ii) requires that the Federal rate be adjusted so that aggregate payments for the fiscal year based on the Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the geographic adjustment factor (GAF) are projected to equal aggregate payments that would have been made on the basis of the Federal rate without such changes.

Since we implemented a separate geographic adjustment factor for Puerto Rico, we apply separate budget neutrality adjustments for the national geographic adjustment factor and the Puerto Rico geographic adjustment factor. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier since the geographic adjustment factor for Puerto Rico was implemented in FY 1998.

In the past, we used the actuarial capital cost model (described in Appendix B of the August 1, 2001 final rule (66 FR 40099)) to estimate the aggregate payments that would have been made on the basis of the Federal rate with and without changes in the DRG classifications and weights and in the GAF to compute the adjustment required to maintain budget neutrality for changes in DRG weights and in the GAF. During the transition period, the capital cost model was also used to estimate the regular exceptions payment adjustment factor. As we explain in section III.A.4. of this Addendum, beginning in FY 2003 an adjustment for regular exceptions is no longer necessary. Therefore, we are no longer using the capital cost model. Instead, we are using historical data based on hospitals' actual cost experiences to determine the exceptions adjustment factor for special exception payments.

To determine the factors for FY 2003, we compared (separately for the national rate and the Puerto Rico rate) estimated aggregate Federal rate payments based on the FY 2002 DRG relative weights and the FY 2002 GAF to estimated aggregate Federal rate payments based on the FY 2003 relative weights and the FY 2003 GAF. For FY 2002, the budget neutrality adjustment factors were 0.9927 for the national rate and 0.9916 for the Puerto Rico rate (see the August 1, 2001 final rule (66 FR 40101)). In making the comparison, we set the regular and special exceptions reduction factors to 1.00.

To achieve budget neutrality for the changes in the national GAF, based on calculations using updated data, we are applying an incremental budget neutrality adjustment of 0.9991 for FY 2003 to the previous cumulative FY 2002 adjustment of (0.9927), yielding a cumulative adjustment of 0.9918 through FY 2003. For the Puerto Rico GAF, we are applying an incremental budget neutrality adjustment of 1.0081 for FY 2003 to the previous cumulative FY 2002 adjustment (0.9916), yielding a cumulative adjustment of 0.9997 through FY 2003.

We then compared estimated aggregate Federal rate payments based on the FY 2002 DRG relative weights and the FY 2002 GAF to estimated aggregate Federal rate payments based on the FY 2003 DRG relative weights and the FY 2003 GAF. The incremental adjustment for DRG classifications and changes in relative weights is 0.9966 both nationally and for Puerto Rico. The cumulative adjustments for DRG classifications and changes in relative weights and for changes in the GAF through FY 2003 are 0.9885 nationally and 0.9963 for Puerto Rico. The following table summarizes the adjustment factors for each fiscal year:

BUDGET NEUTRALITY ADJUSTMENT FOR DRG RECLASSIFICATIONS AND RECALIBRATION AND THE GEOGRAPHIC ADJUSTMENT FACTORS

Fiscal year	National			Cumulative	Puerto Rico			Cumulative
	Incremental adjustment				Incremental adjustment			
	Geographic adjustment factor	DRG Reclassifications and recalibration	Combined		Geographic adjustment factor	DRG Reclassifications and recalibration	Combined	
1992	.....	.....	.....	1.00000	.....	.....	.....	.....
1993	.....	.....	0.99800	0.99800	.....	.....	.....	.....
1994	.....	.....	1.00531	1.00330	.....	.....	.....	.....
1995	.....	.....	0.99980	1.00310	.....	.....	.....	.....
1996	.....	.....	0.99940	1.00250	.....	.....	.....	.....
1997	.....	.....	0.99873	1.00123	.....	.....	.....	.....
1998	.....	.....	0.99892	1.00015	.....	.....	.....	1.00000
1999	0.99944	1.00335	1.00279	1.00294	0.99898	1.00335	1.00233	1.00233
2000	0.99857	0.99991	0.99848	1.00142	0.99910	0.99991	0.99901	1.00134
2001[1]	0.99782	1.00009	0.99791	0.99933	1.00365	1.00009	1.00374	1.00508
2001[2]	[3]0.99771	[3]1.00009	[3]0.99780	0.99922	[3]1.00365	[3]1.00009	[3]1.00374	1.00508
2002	[4]0.99666	[4]0.99668	[4]0.99335	0.99268	[4]0.98991	[4]0.99668	[4]0.99662	0.99164
2003	0.99915	0.99662	0.99577	0.98848	1.00809	0.99662	1.00468	0.99628

[1] Factors effective for the first half of FY 2001 (October 2000 through March 2001).
[2] Factors effective for the second half of FY 2001 (April 2001 through September 2001).
[3] Incremental factors are applied to FY 2000 cumulative factors.
[4] Incremental factors are applied to the cumulative factors for the first half of FY 2001.

The methodology used to determine the recalibration and geographic (DRG/GAF) budget neutrality adjustment factor for FY 2003 is similar to that used in establishing budget neutrality adjustments under the prospective payment system for operating

costs. One difference is that, under the operating prospective payment system, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the DRG relative weights. Under the capital prospective payment system, there is a single DRG/GAF budget neutrality adjustment factor (the national rate and the Puerto Rico rate are determined separately) for changes in the GAF (including geographic reclassification) and the DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for serving low-income patients, indirect medical education payments, or the large urban add-on payments.

For FY 2002, we calculated a GAF/DRG budget neutrality factor of 0.9934. In the proposed rule, we proposed a GAF/DRG budget neutrality factor of 1.0024. For this final rule, based on updated data, we are establishing a GAF/DRG budget neutrality factor of 0.9957 for FY 2003. The GAF/DRG budget neutrality factors are built permanently into the rates; that is, they are applied cumulatively in determining the Federal rate. This follows from the requirement that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAF. The incremental change in the adjustment from FY 2002 to FY 2003 is 0.9957. The cumulative change in the rate due to this adjustment is 0.9885 (the product of the incremental factors for FY 1993, FY 1994, FY 1995, FY 1996, FY 1997, FY 1998, FY 1999, FY 2000, FY 2001, FY 2002, and FY 2003: $0.9980 \times 1.0053 \times 0.9998 \times 0.9994 \times 0.9987 \times 0.9989 \times 1.0028 \times 0.9985 \times 0.9979 \times 0.9934 \times 0.9957 = 0.9885$).

This factor accounts for DRG reclassifications and recalibration and for changes in the GAF. It also incorporates the effects on the GAF of FY 2003 geographic reclassification decisions made by the MGCRB compared to FY 2002 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors or in the large urban add-on.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) requires that the standard capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for both regular exceptions and special exceptions under § 412.348 relative to total capital prospective payment system payments. In estimating the proportion of regular exceptions payments to total capital prospective payment system payments during the transition period, we used the actuarial capital cost model originally developed for determining budget neutrality (described in Appendix B of the August 1, 2001 final rule (66 FR 40099)) to determine the exception adjustment factor, which was applied to both the Federal and hospital-specific rates.

An adjustment for regular exceptions is no longer necessary in determining the FY 2003 capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001. Accordingly, as we explained in the August 1, 2001 final rule (66 FR 39949), in FY 2003 and subsequent fiscal years, no payments will be made under the regular exceptions provision. However, in accordance with § 412.308(c), we still need to compute a budget neutrality adjustment for special exception payments under § 412.348(g). We describe our methodology for determining the special exceptions adjustment used in establishing the FY 2003 capital Federal rate below.

Under the special exceptions provision specified at § 412.348(g)(1), eligible hospitals include SCHs, urban hospitals with at least 100 beds that have a disproportionate share percentage of at least 20.2 percent or qualify for DSH payments under § 412.106(c)(2), and hospitals with a combined Medicare and Medicaid inpatient utilization of at least 70 percent. An eligible hospital may receive special exception payments if it meet (1) a project need requirement as described at § 412.348(g)(2), which, in the case of certain urban hospitals, includes an excess capacity test as described at § 412.348(g)(4); (2) an age of assets test as described at § 412.348(g)(3); and (3) a project size requirement as described at § 412.348(g)(5).

As we explained in the August 1, 2001 final rule (66 FR 39912–39914), in order to determine the estimated proportion of special exceptions payments to total capital payments, we attempted to identify the universe of eligible hospitals that may potentially qualify for special exception payments. First, we identified hospitals that met the eligibility requirements at § 412.348(g)(1). Then we determined each hospital's average fixed asset age in the earliest available cost report starting in FY 1992 and subsequent fiscal years. For each of those hospitals, we calculated the average fixed asset age by dividing the accumulated depreciation by the current year's depreciation. In accordance with § 412.348(g)(3), a hospital must have an average age of buildings and fixed assets above the 75th percentile of all hospitals in the first year of the capital prospective payment system. In the September 1, 1994 final rule (59 FR 45385), we stated that, based on the June 1994 update of the cost report files in HCRIS, the 75th percentile for buildings and fixed assets for FY 1992 was 16.4 years. However, we noted that we would make a final determination of that value on the basis of more complete cost report information at a later date. In the August 29, 1997 final rule (62 FR 46012), based on the December 1996 update of HCRIS and the removal of outliers, we finalized the 75th percentile for buildings and fixed assets for FY 1992 as 15.4 years. Thus, we eliminated any hospitals from the potential universe of hospitals that may qualify for special exception payments if its average age of fixed assets did not exceed 15.4 years.

For the hospitals remaining in the potential universe, we estimated project-size by using the fixed capital acquisitions shown on Worksheet A7 from the following HCRIS cost reports updated through June 2002.

PPS year	Cost reporting periods beginning in . . .
IX	FY 1992
X	FY 1993
XI	FY 1994
XII	FY 1995
XIII	FY 1996
XIV	FY 1997
XV	FY 1998
XVI	FY 1999
XVII	FY 2000

Because the project phase-in may overlap 2 cost reporting years, we added together the fixed acquisitions from sequential pairs of cost reports to determine project size. Under § 412.348(g)(5), the hospital's project cost must be at least $200 million or 100 percent of its operating cost during the first 12-month cost reporting period beginning on or after October 1, 1991. We calculated the operating costs from the earliest available cost report starting in FY 1992 and later by subtracting inpatient capital costs from inpatient costs (for all payers). We did not subtract the direct medical education costs as those costs are not available on every update of the HCRIS minimum data set. If the hospital met the project size requirement, we assumed that it also met the project need requirements at § 412.348(g)(2) and the excess capacity test for urban hospitals at § 412.348(g)(4).

Because we estimate that so few hospitals will qualify for special exceptions, projecting costs, payments, and margins would result in high statistical variance. Consequently, we decided to model the effects of special exceptions using historical data based on hospitals' actual cost experiences. If we determined that a hospital may qualify for special exceptions, we modeled special exceptions payments from the project start date through the last available cost report (FY 1999). (Although some FY 2000 cost reports are available in HCRIS, only a few hospitals have submitted FY 2000 costs. Consequently, too few cost reports are available to reliably model FY 2000 special exceptions payments.) For purposes of modeling we used the cost and payment data on the cost reports from HCRIS assuming that special exceptions would begin at the start of the qualifying project. In other words, when modeling costs and payment data, we ignored any regular exception payments that these hospitals may otherwise have received as if there had not been regular exceptions during the transition period. In projecting an eligible hospital's special exception payment, we applied the 70-percent minimum payment level, the cumulative comparison of current year capital prospective payment system payments and costs, and the cumulative operating margin offset (excluding 75 percent of operating DSH payments).

Our modeling of special exception payments for FY 2003 produced the following results: